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ABSTRACT

This special issue is designed for those who want to know all they can about the new federal requirements for nutrition information on food labels. Nine articles are included. "Good Reading for Good Eating" (Paula Kurtzweil) addresses mandatory nutrition labeling, the nutrition panel, nutrient content and health claims, and ingredient labeling. "Cooking Up the New Food Label" (Judith E. Foulke) describes the process of writing the regulations. "Look for 'Legit' Health Claims on Foods" (Dixie Farley) covers definitions and restrictions, new claims, guidelines for using health claims, and denied claims. "A Little 'Lite' Reading" (Dori Stehlin) focuses on 11 core terms related to nutrient content claims: free, low, lean, extra lean, high, good source, reduced, less, light, fewer, and more. "'Nutrition Facts' to Help Consumers Eat Smart" (Kurtzweil) describes the format of the new nutrition label, called 'Nutrition Facts.' "'Daily Values' Encourage Healthy Diet" (Kurtzweil) focuses on the 'daily values' term and describes two sets of reference values for nutrients that serve as the basis for calculating percent daily values--Daily Reference Values and Reference Daily Intakes. "Ingredient Labeling: What's in a Food?" (Marian Segal) addresses the requirement that ingredients for all standardized foods be listed on the label. "Nutrition Info Available for Raw Fruits, Vegetables, Fish" (Kurtzweil) concerns guidelines for voluntary labeling of raw produce and fish. "The Food Pyramid-Food Label Connection" (Etta Saltos) discusses how to use the label information to follow the Dietary Guidelines for Americans. (YLB)

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FDA CONSUMER

THE MAGAZINE OF THE U.S. FOOD AND DRUG ADMINISTRATION

AN *FDA CONSUMER* SPECIAL REPORT

FOCUS ON FOOD LABELING

READ THE LABEL



SET A HEALTHY TABLE

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AN FDA CONSUMER SPECIAL REPORT

FOCUS ON FOOD LABELING

May 1993

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TAKING THE GUESSWORK OUT OF GOOD NUTRITION

The documents that spell out the new federal requirements for nutrition information on food labels are daunting in their length and complexity: They consume hundreds of pages in the *Federal Register*.

The regulations themselves take up only a small part of that opus. The rest is background information. It explains, first of all, why the Food and Drug Administration and the U.S. Department of Agriculture took on the task of making the most sweeping changes to this country's food labeling in a generation.

It also explains how the agencies reached their decisions on the thousands of issues—major and minor—involved in the new food label. The documents offer a classic case study in the making of health regulations. The new food labels will provide more help than ever before for consumers trying to eat healthy. There will now be a wealth of information, not just on the side or back of the package, but on the front panel, too, about how virtually every food product contributes—for better or worse—to our daily diet.

It would be a terrible waste if all the thought, planning and effort that went into the new food label went for naught because consumers either didn't know there was something new, or didn't bother to use it in planning their daily diet.

That's where this special issue of *FDA Consumer* magazine comes in. It's designed for those who want to know all

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they can about the new labeling requirements, without wading through those hundreds of pages of the *Federal Register* on their own.

To reach even more consumers than is possible with this magazine, FDA, USDA, and many other public and private sector organizations are conducting major public education campaigns with a wide variety of materials—print, video and other. The goal is to carry the message of the new food label to a target audience of a quarter of a billion people—simply defined as “everyone who eats.”

We hope that this publication will not only be helpful to consumers, but will also serve as a useful tool for those who will be joining in the effort to educate the public: teachers, journalists, doctors, nutritionists, dietitians, other health professionals, and health educators. We have covered all the major facets of the new regulations—the new nutrition panel, health claims, nutrient content descriptors, among others—in enough detail to make them understandable yet not overwhelming.

What the new labeling requirements boil down to is this:

- Nutrition information will be virtually universal in the marketplace; almost every food will carry it.
- That information will be up-to-date with the dietary needs of Americans in the 1990s.
- Labels will show how each food fits into an overall healthy diet, nutrient by nutrient.
- Credibility will be restored to the often hyperbolic marketing claims such as “light,” “fat-free,” “low-calorie,” and “high-fiber.”

In short, the new food label will take the guesswork out of good nutrition, if shoppers choose to use the information that will now be—literally—at their fingertips.

We hope this special issue of *FDA Consumer* helps make that happen, so that the most bountiful, safest food supply in the world will also be the healthiest.

FOCUS ON FOOD LABELING

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Good Reading For Good Eating

by Paula Kurtzweil

It may not have the power of a Pulitzer prize-winning novel or the luridness of a checkout counter tabloid, but the new food label still promises to make for good reading.

New regulations from FDA and the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture see to that. They ensure that:

- nutrition information will appear in the labeling of almost all foods
- labels will provide information on how the food fits into an overall daily diet
- labels will include information on the amount per serving of saturated fat, cholesterol, dietary fiber, and other nutrients of health concern to today's consumers
- terms used to describe a food's nutrient content—"light," "fat-free," and "low-calorie," for example—will meet government definitions so that they mean the same for any product on which they appear
- health claims about the relationship between a nutrient or food and a disease that



"The new food label is an unusual opportunity to help millions of Americans make more informed, healthier food choices."

—David Kessler, M.D., Commissioner of Food and Drugs

are supported by scientific evidence will be allowed for the first time

- serving sizes:
 - are more consistent across product lines to make comparison shopping easier
 - are expressed in common household and metric measures
 - better reflect the amounts people really eat.

There will be many more products with labels to read because the regulations, for the first time, make nutrition labeling mandatory for almost all processed foods. Also, uniform point-of-purchase nutrition information will accompany many fresh foods, such as fruits and vegetables and raw fish, meat and poultry.

The new food label is reading that can be put to good use, too, because it's designed to help clear up much of the confusion that has prevailed on supermarket shelves. It also can help consumers choose more healthful diets. And it can serve as an incentive to food companies to improve the nutritional qualities of their products.

"[This isn't] just another government program," said FDA Commissioner David Kessler, M.D. "The new food label is an unusual opportunity to help millions of Americans make more informed, healthier food choices."

"We expect the labels also will provide more food companies with an incentive to improve the nutritional quality of their products," said H. Russell Cross, Ph.D., FSIS administrator.

The new labels will start to appear on products this year, although manufacturers

have until May 8, 1994, to comply with most of FDA's new labeling requirements and until July 6, 1994, to comply with FSIS', which cover processed meat and poultry products. (FDA regulates labeling of most food products, except for meat and poultry products, which fall under FSIS' jurisdiction.)

The FSIS voluntary point-of-purchase nutrition information program for raw meat and poultry goes into effect then, too. Point-of-purchase information for fresh produce and raw fish has been available in some grocery stores since November 1991. (See "Nutrition Info Available for Raw Fruits, Vegetables, Fish" on page 51.)

Advertising is not covered by the Nutrition Labeling and Education Act, but the Federal Trade Commission has indicated it may apply the same criteria to advertising that FDA and FSIS do to labels.

A Look Back

The changes will mark the first extensive renovation of the food label since 1974, when FDA and USDA established voluntary nutrition labeling and began requiring nutrition information on labels of products that contain added nutrients or that carry nutrition claims. Other than adding sodium as a mandatory and potassium as a voluntary component to the list of nutrients allowed in voluntary nutrition labeling in 1984, the nutrition label has remained essentially the same all that time.

Nutrition labeling wasn't ignored during the interim, though, as Congress, regulators, and consumer and industry groups

put forth ideas to overhaul it. Their efforts intensified as consumers became more interested in nutrition, and food marketing strategies began to focus on that interest.

That marketing trend represented a departure from usual practice, according to Ed Scarbrough, Ph.D., director of the Office of Food Labeling in FDA's Center for Food Safety and Applied Nutrition.

"The line from industry used to be: 'Nutrition won't sell food. It's price, taste and convenience,'" he said. "By the time we got into the 1980s, nutrition clearly was selling products. Industry recognized this and started making claims about the food."

That was both good and bad, Scarbrough said. On the one hand, it gave consumers more information about nutrition. But on the other, claims got pushed to their outer limits as manufacturers scrambled to gain a competitive edge for their products.

"Consumers reacted to that," he said. "They couldn't believe many of the claims being made."

At about the same time, the Surgeon General of the U.S. Public Health Service and the National Academy of Sciences' National Research Council released two reports that lent strong support to development of a new food label. These reports—the 1988 *Surgeon General's Report on Nutrition and Health*, and the 1989 *National Research Council's Diet and Health: Implications for Reducing Chronic Disease Risk*—concluded that evidence substantiates an association between diet and risk of chronic disease and recommended similar dietary changes.

There will be many more products with labels to read because the regulations, for the first time, make nutrition labeling mandatory for almost all processed foods.

Those recommendations reflected what many public health experts had been saying for years: for example, that Americans should reduce their intake of fat (especially saturated fat), cholesterol and sodium; maintain appropriate body weight; and consume adequate amounts of calcium and fiber. The National Research Council's report went so far as to recommend quantitative amounts for certain nutrients.

It soon became apparent, however, that the current food label did not offer enough information to help consumers follow those guidelines. That, coupled with often questionable marketing practices, led to the first serious effort to revamp the food label.

Developing a New Label

The effort got under way in 1989, when FDA published an advance notice of proposed rule-making and, with FSIS, held nationwide hearings to find out what consumers, food manufacturers, and health professionals wanted on the food label.

Early in 1990, FDA began publishing proposals for new food labeling regulations that would, among other things, mandate nutrition labeling for almost all processed foods, limit health claims, establish reference Daily Values for certain nutrients, and define serving sizes.

Later that year, the Nutrition Labeling and Education Act (NLEA) became law, mandating numerous changes in food labeling. (The law does not cover meat and poultry products.)

NLEA resembles FDA's 1990 propos-

als in many ways. For example, it mandates nutrition labeling for almost all processed foods regulated by FDA and authorizes appropriate health claims on the labels of such products. It goes one step further by calling for activities to educate consumers about nutrition information on the label and the importance of using that information in maintaining healthful dietary practices.

According to John Vanderveen, Ph.D., director of FDA's Office of Plant and Dairy Foods and Beverages, the law makes the United States the first country in the world to have mandatory nutrition labeling and to allow health claims on food labels. "We've been pioneers," he said.

In November 1991, FDA announced proposals to implement many of the law's provisions. At the same time, FSIS issued parallel proposed regulations for meat and poultry.

Both agencies reviewed tens of thousands of public comments on the proposals before publishing the final regulations in the Jan. 6, 1993, *Federal Register*.

As allowed under NLEA, FDA delayed the date by which manufacturers must comply with the nutrition labeling and nutrient content claims provisions of NLEA by one year from the statutory effective date of May 8, 1993. FDA found that the earlier date would cause "undue economic hardship" on industry. FSIS postponed implementation of its regulations until July 1994 for the same reason.

However, consumers may start to see new labels this year, if, as expected,

manufacturers seek to make their products among the first with the new food label.

Briefly, here is what consumers can expect to see:

Mandatory Nutrition Labeling

About 90 percent of processed food will carry nutrition information. Among the exemptions will be plain coffee and tea; some spices, flavorings and other foods that contain no significant amounts of nutrients; ready-to-eat food prepared primarily on site, such as deli and bakery items; restaurant food; bulk food that is not resold; and food produced by small businesses. (As required under NLEA, FDA defines a small business as one with food sales of less than \$50,000 a year or total sales of less than \$500,000. FSIS defines a small business as one that employs 500 or fewer people and produces no more than a certain poundage of product.)

Foods in small packages (generally those no larger than a package of Life Savers, or meat and poultry products less than a half ounce) do not have to have nutrition information on their labels unless they make a nutrition claim. However, FDA-regulated products must carry a telephone number or address consumers can use to get required nutrition information.

Nutrition information is voluntary for many raw foods: the 20 most frequently eaten raw fruits, vegetables and fish, under FDA's voluntary point-of-purchase nutrition information program, and the 45 major cuts of meat and poultry, under USDA's voluntary point-of-purchase program. (Continued on page 12)

MILESTONES IN U.S. FOOD LABELING

1906 The Federal Food and Drugs Act and the Federal Meat Inspection Act authorize the federal government to regulate the safety and quality of food. The responsibility falls to the U.S. Department of Agriculture and its Bureau of Chemistry, FDA's predecessor.

1913 The Gould Amendment requires food packages to state the quantity of contents.

1924 In *U.S. v. 95 Barrels Alleged Apple Cider Vinegar*, the Supreme Court rules that the Food and Drugs Act condemns every statement, design or device which may mislead, misdirect or deceive, even if technically true.

1938 The Federal Food, Drug, and Cosmetic Act replaces the 1906 Food and Drugs Act. Among other things, it requires the label of every processed, packaged food to contain the name of the food, its net weight, and the name and address of the manufacturer or distributor. A list of ingredients also is required on certain products. The law also prohibits statements in food labeling that are false or misleading.

1950 The Oleomargarine Act requires prominent labeling of colored oleomargarine to distinguish it from butter.

1957 The Poultry Products Inspection Act authorizes USDA to regulate, among other things, the labeling of poultry products.

1966 The Fair Packaging and Labeling Act requires all consumer products in interstate commerce to contain accurate information and to facilitate value comparisons.

1969 The White House Conference on Food, Nutrition, and Health addresses deficiencies in the U.S. diet. It recommends that the federal government consider developing a system for identifying the nutritional qualities of food.

1973 FDA issues regulations requiring nutrition labeling on food containing one or more added nutrients or whose label or advertising includes claims about the food's nutritional properties or its usefulness in the daily diet. Nutrition labeling is voluntary for almost all other foods.

1975 Voluntary nutrition labeling, postponed from its originally planned 1974 date, goes into effect.

1984 FDA adds sodium to the list of required, and potassium to the list of optional, nutrients on the nutrition panel. Effective in 1985, the new regulation also defines terms, such as "low sodium," that may be used on labels to make sodium-content claims.

1988 Surgeon General C. Everett Koop releases *The Surgeon General's Report on Nutrition and Health*, the federal government's first formal recognition of the role of diet in certain chronic diseases.

1989 The National Research Council of the National Academy of Sciences issues *Diet and Health: Implications for Reducing Chronic Disease Risk*, which presents additional evidence of the growing acceptance of diet as a factor in the development of chronic diseases, such as coronary heart disease and cancer.

Under contract with FDA and USDA's Food Safety and Inspection Service (FSIS), the Food and Nutrition Board of the National Academy of Sciences convenes a committee to consider how food labels could be improved to help consumers adopt or adhere to healthy diets. Its

recommendations are presented in *Nutrition Labeling: Issues and Directions for the 1990s*.

FDA publishes an advance notice of proposed rule-making on food labeling and, with FSIS participating, holds a series of four public hearings around the country.

1990 FDA proposes extensive food labeling changes, which include mandatory nutrition labeling for most foods, standardized serving sizes, and uniform use of health claims.

The Nutrition Labeling and Education Act reaffirms the legal basis for FDA's labeling initiative and establishes an explicit timetable.

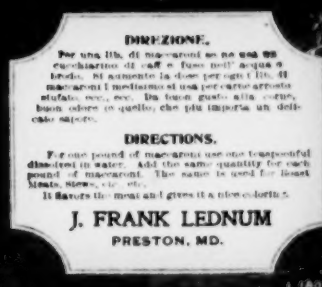
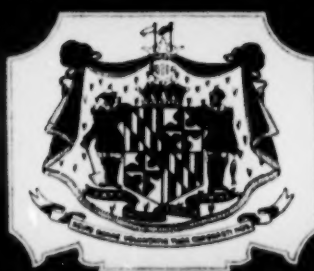
1991 FDA issues more than 20 proposals to implement NLEA. In addition, the agency issues a final rule that sets up a voluntary point-of-purchase nutrition information program for raw produce and fish. FSIS unveils its proposals for mandatory nutrition labeling of processed meat and poultry and voluntary point-of-purchase nutrition information for raw meat and poultry.

1992 FDA's voluntary point-of-purchase nutrition information program for fresh produce and raw fish goes into effect.

1993 FDA issues the final regulations implementing NLEA. Regulations covering health claims become effective May 8, 1993. Those pertaining to nutrition labeling and nutrient content claims are effective May 8, 1994.

FSIS issues regulations for nutrition labeling of meat and poultry, effective July 6, 1994.

—P.K.



The 1938 law cracked down on many of the abuses shown in this label from the early 1900s, such as using a foreign language to give apparently mandatory information, omitting the name of the product and the quantity of contents, giving an apparently incomplete list of ingredients, and not specifically stating the manufacturer or distributor's name and place of business. (Photo © 1984)



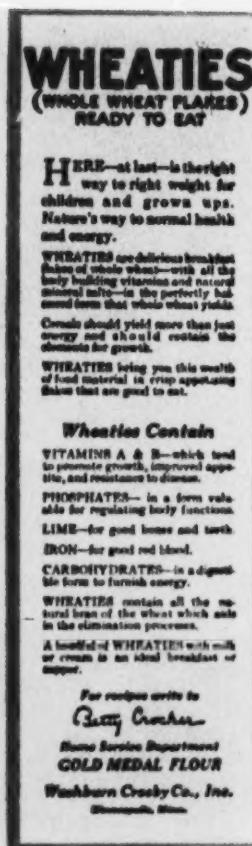
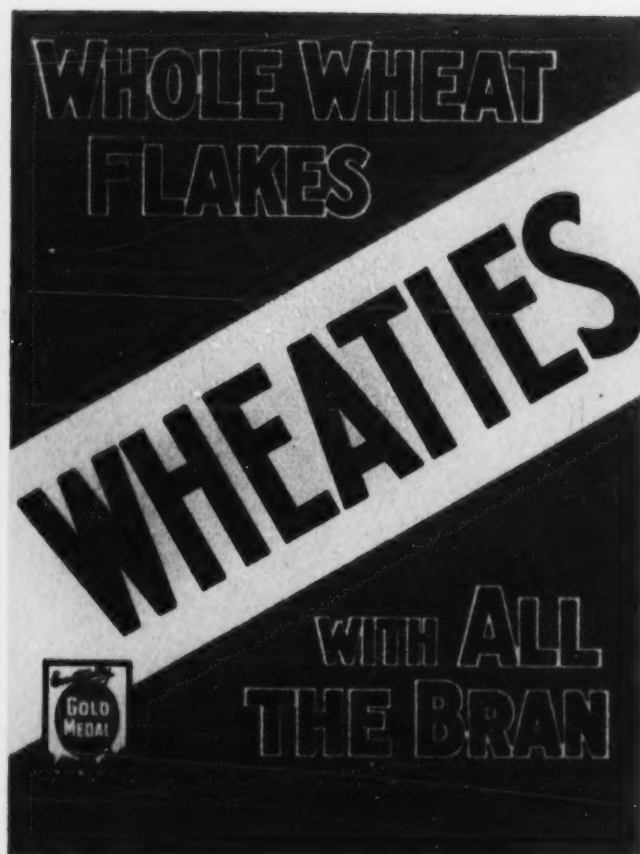
Under the 1906 Act, there was nothing to prevent manufacturers from making claims, such as the one on the far right of this label, implying that a food was certified or approved by FDA. The 1938 Federal Food, Drug, and Cosmetic Act outlawed these and other false and misleading claims, and they remain illegal today.

(Photo © 1984)

Until 1906, food labels were not required to give any information, so this one didn't. (Photo © 1984)

Photos courtesy of the Smithsonian Institution

The changes will mark the first extensive renovation of the food label since 1974.



Although health claims proliferated in the 1980s, they've been around for years, as the right panel of this 1925 label for Wheaties shows.

(Photo courtesy of General Mills Inc.)

(Continued from page 9)

Although voluntary, the programs for raw produce, meat, fish, and poultry carry strong incentives for retailers to participate. Guidelines state that if voluntary compliance is found to be insufficient, the agencies may move to make it mandatory.

Nutrition Panel

A revised list of nutrients—selected because of their relationship to current health concerns—will appear on the nutrition panel. (See “‘Nutrition Facts’ to Help Consumers Eat Smart” on page 34.) Some of the nutrients are carryovers from the previous label: calories, total fat, total carbohydrate, protein, sodium, vitamins A and C, calcium, and iron. The new ones are calories from fat, saturated fat, cholesterol, sugars, and dietary fiber. No longer required are thiamin, riboflavin and niacin because deficiencies of these vitamins are no longer considered significant public health problems. However, manufacturers may list these and other nutrients if they choose, subject to certain conditions.

Serving sizes specified on labels now will be more uniform across all product lines so that consumers can more easily compare the nutritional qualities of similar products. They also will be closer to the amounts people actually eat.

The amount of certain nutrients will be expressed not only in terms of the amount per serving but also in terms of a percent of a new dietary reference value, called the Daily Value. The “percent Daily Values” will be based on a 2,000-calorie diet.

Serving sizes specified on labels now will be more uniform across all product lines so that consumers can more easily compare the nutritional qualities of similar products.

(See " 'Daily Values' Encourage Healthy Diet" on page 40.)

Requiring nutrients to be declared as a percent of the Daily Value is intended to help consumers understand the role of individual foods in the context of the total daily diet.

Nutrient Content Claims

Any term used to describe the nutrient content of a food will mean the same on every product on which it appears. Also, the list of acceptable claims now includes such descriptors as "free," "low," "light" (or "lite"), "reduced," "less," and "high." "Lean" and "extra lean" also have been defined and will apply specifically to the fat content of meat, including game meat, poultry, and fish. (See "A Little 'Lite' Reading" on page 29.)

Health Claims

Claims linking a nutrient or a food to the risk of a disease or health-related condition now will be allowed only under certain circumstances on FDA-regulated products. FDA will allow statements about the relationships between:

- calcium and osteoporosis
- fat and cancer
- saturated fat and cholesterol and coronary heart disease (CHD)
- fiber-containing grain products, fruits and vegetables and cancer
- fruits, vegetables and grain products that contain fiber, particularly soluble fiber, and CHD

- sodium and hypertension
- fruits and vegetables and cancer.

There are strict requirements about when and how these claims can be used. (See "Look for 'Legit' Health Claims on Foods" on page 20.)

Ingredient Labeling

Full ingredient labeling will appear on all processed, packaged foods, including standardized foods such as mayonnaise, macaroni and bread, which previously were exempt.

Also, for the first time, the ingredient list will include, when appropriate:

- FDA-certified color additives, such as FD&C Yellow No. 6, by name
- sources of protein hydrolysates, which are used in many foods as flavor enhancers
- declaration of caseinate as a milk derivative in foods that claim to be nondairy, such as coffee whiteners.

In addition, beverages that claim to contain juices must declare the total percentage of juice on the information panel. (See "Ingredient Labeling: What's in a Food?" on page 46.)

Economic Impact

It is estimated that the new food label will cost FDA-regulated food processors between \$1.4 billion and \$2.3 billion over the next 20 years. However, the benefits to public health—measured in monetary terms—are estimated to well exceed the costs. Potential benefits include decreased

rates of coronary heart disease, cancer, osteoporosis, obesity, high blood pressure, and allergic reactions to food.

Public Education

To help consumers get the most from the new food label, FDA and USDA have embarked on a multi-year food labeling education campaign. The campaign involves participation by consumer, trade and health groups, as well as by other government agencies. Its purpose is to increase consumers' knowledge and effective use of the new food label and assist them in making accurate and sound dietary choices in accordance with the Dietary Guidelines for Americans.

"The food label of the future will have more information and be more complicated," FDA's Scarbrough said. "Its usefulness will be diminished unless consumers are taught what to do with the information."

Fred Shank, Ph.D., director of FDA's Center for Food Safety and Applied Nutrition, and other nutrition experts acknowledge that the task of teaching consumers how to use the new label will be formidable.

"It's been a long haul," Shank said about efforts to revamp the label. "But the greatest challenge lies ahead—in educating consumers." ■

Paula Kurtzweil is a member of FDA's public affairs staff.

Cooking Up the New Food Label

by Judith E. Foulke



READING THE NEW FOOD LABELS REQUIRED ON ALMOST ALL FOODS WILL MAKE PLANNING HEALTHY DIETS EASIER FOR CONSUMERS. WRITING THE REGULATIONS THAT SPELL OUT WHAT SHOULD BE ON THOSE LABELS HAS BEEN EVERYTHING BUT EASY FOR THE RULE-MAKERS.

ASK ANY NUMBER OF FOOD AND DRUG ADMINISTRATION AND U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE (FSIS) STAFFERS

WHO WERE INVOLVED IN WRITING THE REGULATIONS.

THEY'LL SAY THAT IN ALMOST EVERY INSTANCE, BEFORE PEN MET PAPER THERE WAS A TUG-OF-WAR BETWEEN WHAT THE LAW REQUIRES AND THE MANY OPINIONS ABOUT THE MOST PRACTICAL WAY TO PRESENT NUTRITION INFORMATION ON THE FOOD LABEL. BY THE

TIME REGULATIONS WERE WRITTEN, MANY COMPROMISES HAD BEEN MADE. HOWEVER, BOTH AGENCIES BELIEVE THAT NONE OF THE TRADEOFFS WAS AT THE EXPENSE OF



F. Edward Scarbrough
Director, Office of Food Labeling



Margaret O'K. Glavin
*Deputy Administrator,
Regulatory Programs, USDA*

*"What neither agency
wanted to do was to tell
consumers exactly what
they should be eating."*

*—F. Edward Scarbrough, Ph.D.,
FDA's Office of Food Labeling*

consumer interests or resulted in an excessive burden to the food industry.

First on FDA's and FSIS' agenda for food label reform was to solicit advice from consumers, health professionals in and out of government, and members of the food industry. (See "Good Reading for Good Eating," on page 7.)

"Having the clear legal authority paved the way for us to write the regulations," says F. Edward Scarbrough, Ph.D., director of FDA's Office of Food Labeling, who coordinated the Nutrition Labeling and Education Act (NLEA) rule-making process in the Center for Food Safety and Applied Nutrition. It also sped up the entire project because it established deadlines. For example, it required FDA to propose regulations by November 1991.

"That was a blessing and a curse," says Scarbrough. "The timetable forced us to get the proposals out without a lot of over-review, re-drafting, and going back and forth, but staffers put in long hours, often working on weekends, to meet the one-year deadline."

By November 1991, FDA had published 26 proposals. At the same time, FSIS published a parallel proposal for the nutrition labeling of meats and poultry.

Although meat and poultry products were not covered by NLEA, FSIS shared FDA's concern for consistent labeling re-

quirements so that all foods would carry the same type of information and labels would appear at about the same time. FSIS Deputy Administrator Margaret O'K. Glavin, leader of USDA's label reform effort for more than three years, says, "The combined effort was a success because of the excellent staff work of FSIS and FDA. That's what made it possible."

In January 1992, FDA and FSIS called a public hearing on the proposals. Ninety-two representatives from the food industry, the scientific community, and consumer groups presented their comments in person to a panel of FDA and FSIS officials.

In addition to the oral comments, FDA received more than 40,000 others in writing, the largest number ever received in response to an FDA proposed regulation. About 30,000 were form letters from organized campaigns.

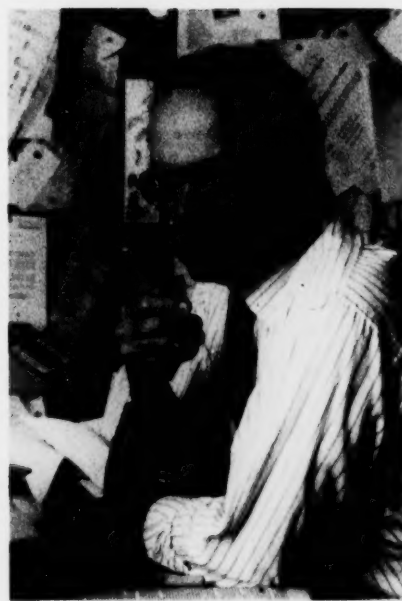
FSIS received 1,109 comments. "Consumer groups, industry, and medical groups overwhelmingly asked for 'harmonization' of the FDA and FSIS labels," says Cheryl Wade, chief, FSIS Nutrition Branch and coordinator of the rule-making process for FSIS.

Dealing with Details

The details called for by NLEA were often a problem for FDA rule-makers,



Youngmee K. Park
*Nutritionist, Office of
Special Nutritionals*



Gerad L. McCowin
*Special Assistant to the Director,
Office of Food Labeling*

FDA and FSIS relied on a great number of outside resources. Both used the expertise of scientists within their own agencies and from the National Institutes of Health and the Centers for Disease Control and Prevention, and reviewed a number of scientific studies.

says Scarbrough. "For example," he says, "the law says 'the label shall have' and named nutrients. One of the nutrients named was complex carbohydrates." In order to enforce the law, Scarbrough says, FDA would have had to come up with a way to measure complex carbohydrates.

"The problem is," he says, "there's no good definition for complex carbohydrates. Had we been working on nutrient list requirements without NLEA, we would not have included complex carbohydrates—we might have made a more general term, such as 'carbohydrates other than sugar'."

FSIS had fewer constraints than FDA because FSIS was not bound by the labeling law. However, in order to provide consistent nutrition information on all foods, FSIS rule-makers stayed in tune with NLEA's restrictive details. "For many years we have used prior label approval—a very different system to regulate labeling," Glavin says. "Also, USDA regulates meat and poultry, so the focus for us was on nutrients such as protein and fat, for example, rather than on fiber," she says.

Troublesome Issues

Most NLEA requirements raised troublesome issues, Scarbrough says. Evaluating health claims as they relate to certain nutrients was one of them. The job

was large—FDA received more than 7,000 public comments concerning its proposal on health claims and each comment was considered.

"Some health claims were very specific, and the evidence was rather limited," he said. "Others were broad, and yet we were given a mandate to come up with a general set of principles and apply them to all 10 claims." Of the 10 diet-health relationships the law required FDA to evaluate, seven were approved. (See "Look for 'Legit' Health Claims on Foods" on page 20.)

FSIS had not finalized a health claims proposal when the final regulations were published, but the agency intends to issue a proposal similar to FDA's final rule.

None of the regulations was easy to write, Scarbrough says. Even when there were general principles that everyone accepted, there were still compromises to be made. The regulation for serving sizes was one such case.

"No one seriously argued that the law shouldn't set serving sizes," Scarbrough says. "But there were arguments with industry about numbers—is it one ounce or an ounce and a half—that sort of thing," he says.

Youngmee Park, Ph.D., of FDA's Office of Special Nutritionals, principal writer of the serving size rule, explains



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"The FDA and food industry cooperative consumer research project to test nutrition label formats is a good example of FDA's commitment to involve interested groups in the process of developing well-reasoned food labeling rules."

—E. Toni Guarino, *Grocery Manufacturers of America*

that foods were grouped into 139 categories. The amount of food customarily eaten per occasion, called the "reference amount," was established for each category, and the agency established rules for converting the reference amounts into label serving sizes.

But special consideration had to be given to certain foods, for example shrimp, that naturally vary in size (how many jumbo-sized shrimp are customarily consumed in one meal as opposed to small-sized shrimp?). There was also a difference in serving sizes when products were aerated, such as whipped peanut butter or aerated waffles.

Healthier Products Encouraged

In developing the regulations, FDA wrote rules that would not limit manufacturers' incentive to produce healthier products in the future, Scarbrough explains. For example, a manufacturer of cooking oils could not label products with claims of reduced risk of heart disease because oil is not a low-fat food. However, if the manufacturer produced a cooking oil lower in saturated fat than its other products, it could make a comparative claim for the nutrient content, calling attention to what the saturated fat level really was.

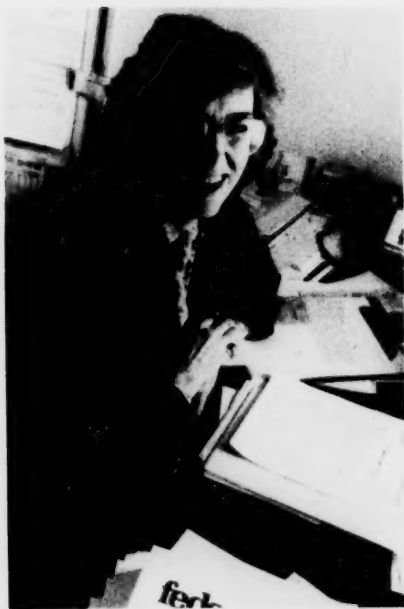
Soy sauce is another product that would not qualify for a health claim because it

has a high sodium content. But under the regulations, a manufacturer could make a "light" soy sauce, making it clear on the label that "light" referred to a reduced sodium content, if that were the case, and if its sodium content were sufficiently reduced from its regular product.

When NLEA was written, says Scarbrough, Congress decided that such information would be useful to consumers—it would balance the picture so that consumers could make choices. Although it may create a cluttered label, the principle is to give complete disclosure about the food and to encourage nutrition information, versus not allowing some products to make any claims at all.

FSIS rule-makers wanted nutrition labeling to facilitate the development of lower-fat meat and poultry products. "Meat and poultry products are good foods," Glavin says. "The descriptors helped us capture the characteristics unique to meat and poultry on the nutrition label," she says.

In its advanced notice of proposed rule-making, FSIS asked for comments on descriptors for meats. The American Heart Association comment suggested definitions for the descriptors so that consumers could rely on the descriptive terms to help them select meat and poultry products with different levels of fat, saturated fat,



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The effort to get NLEA ready for implementation touched almost everyone in FDA's Center for Food Safety and Applied Nutrition, from scientists to secretaries.

and cholesterol. FSIS proposed the AHA-suggested definitions for "lean" and "extra lean." FDA adopted those definitions for the products it regulates, including fish and game meat.

"What neither agency wanted to do was to tell consumers exactly what they should be eating," says Scarbrough. "Industry is very creative describing and promoting their products, and I'm sure manufacturers will come up with ways of doing that without cluttering the label and still stay within the law."

Many Resources Tapped

The effort to get NLEA ready for implementation touched almost everyone in FDA's Center for Food Safety and Applied Nutrition, from scientists to secretaries. Field offices throughout the country were involved also. Charity Singletary, public affairs specialist for FDA's Baltimore district office, says that at a recent national convention of dietitians held in Washington, D.C., "almost every other person who visited our exhibit asked about NLEA." She says from early spring of 1992, all of her public affairs activities, such as exhibits at national meetings and talks to consumer groups and schools, were about NLEA.

In FSIS, staffers devoted thousands of hours, over more than two years, to the la-

bel reform effort. "It was hard work, but because we were working together with equally committed FDA staff, it was also satisfying work," Wade says.

In addition, FDA and FSIS relied on a great number of outside resources. Both used the expertise of scientists within their own agencies and from the National Institutes of Health and the national Centers for Disease Control and Prevention, and reviewed a number of scientific studies, including some from the National Academy of Sciences.

"We listen very carefully to the NAS because it's made up of scientists that come together from all parts of the country," Scarbrough says. "They have prestige and carry a certain amount of 'scientific authority' in the public view. If an NAS committee agrees on something, that's about as close as you can get to the 'general scientific agreement' that NLEA requires. NAS has also worked on Recommended Dietary Allowances for many years and has a lot of experience in that area. And NAS has put together a committee on food labeling with a number of scientific disciplines."

Industry and Consumer Groups React

Scarbrough says FDA worked closely with industry. "In general, the food industry was quite supportive because it knows



*Elizabeth Yetley
Acting Director,
Office of Special Nutritionals*

"Food labeling is a subject we'll continue to revisit for many years to come."

—F. Edward Scarbrough, Ph.D.,

FDA's Office of Food Labeling

that nutrition information is important to consumers, and it sells products," Scarbrough says. "The advantage for industry is that everyone now plays by the same rules."

E. Toni Guarino, vice president and general counsel of the Grocery Manufacturers of America, called the number of regulations required by NLEA and the time frame for issuing them "extraordinary." She said the FDA staff responded with "a high level of dedication and professionalism."

"The FDA and food industry cooperative consumer research project to test nutrition label formats is a particularly good example of FDA's commitment to involve all interested groups in the process of developing well-reasoned food labeling rules that achieve FDA's goals," she says.

FSIS sought to be responsive to industry without conflicting with the public interest. In doing so, FSIS extended the time frame for implementation of its rules, giving industry time for compliance and minimizing costs to consumers. FSIS also made exemptions for firms that met its "small business" definition.

"Consumer groups are generally happy with the law," Scarbrough says. "They'd like us to go even further and be more restrictive with what we're allowing," he says.

Public Voice spokeswoman Patti Morris says her group is pleased that ingredient listings will now be required on standardized foods and that nutrient content claims will be defined.

"FDA, as usual, is trying to strike that balance between consumer interests and what's fair to industry," Scarbrough says. "In general," he adds, "I think both consumer and industry groups support our labeling effort, but each has its own viewpoint about how the effort could have been better or have been done a little differently."

How Final Are the Final Regulations?

Final regulations can be modified. "Industry, or anyone, can petition us to change a regulation," explains Scarbrough. "And NLEA gives us a time frame to react to those petitions."

"With new processed foods coming on the market all the time and changes in eating habits," he says, "I think we'll be re-addressing serving sizes for a long time. The same applies with new health claims or terms a manufacturer would want to use on the label. Food labeling is a subject we'll continue to revisit for many years to come." ■

Judith E. Foulke is a staff writer for FDA Consumer.



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Look For 'LEGIT' Health Claims On Foods

by Dixie Farley

Planning a healthy diet will soon be easier. Beginning this May 8, food labels may provide not only the nutrient content of products but also claims about certain relationships between diet and disease.

As mandated by the Nutrition Labeling and Education Act of 1990, the Food and Drug Administration has issued final food labeling rules for health claims. (See accompanying summary.) The rules, published in the Jan. 6, 1993, *Federal Register*, allow claims about seven relationships:

- calcium and a reduced risk of osteoporosis (a condition of lowered bone mass)
- sodium and an increased risk of hypertension (high blood pressure)
- dietary saturated fat and cholesterol and an increased risk of coronary heart disease
- dietary fat and an increased risk of cancer
- fiber-containing grain products, fruits, and vegetables and a reduced risk of cancer
- fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and a reduced risk of coronary heart disease
- fruits and vegetables and a reduced risk of cancer.

"These rules allow information on food labels that can help to educate the public about recognized diet-disease relationships," says Elizabeth Yetley, Ph.D., acting director of FDA's Office of Special Nutritionals. "Authorized claims must meet requirements to prevent label information that would be false or misleading." Yetley coordinated the agency's health claims evaluation.

Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.



Health claims became a hot issue in the 1980s, when food marketing strategies began reflecting increased recognition of the role of nutrition in promoting health. A 1984 ad campaign by the Kellogg Company for All Bran cereal advised consumers to maintain proper weight and eat a well-balanced diet including low-fat, high-fiber foods, fresh fruits, and vegetables. Stating the National Cancer Institute "believes eating the right foods may reduce your risk of some kinds of cancer," the health message was both attributed to and approved by NCI.

According to an FDA survey by Alan Levy, Ph.D., and Raymond Stokes, Ph.D., sales of high-fiber cereals increased 37 percent within a year as consumers apparently discriminated between high- and low-fiber products.

Under the provisions of the Federal Food, Drug, and Cosmetic Act in effect at that time, FDA took the position that information about a disease on a food label implied that eating the food could beneficially affect the course of the disease. The agency considered such statements to be drug claims.

In 1987, however, in response to developing scientific data on the relationship between diet and disease, FDA proposed changing its policy to permit appropriate health messages on food labels. The agency noted that the rapid increase in information and of public interest in nutrition "argues for recognition and dissemination of such new knowledge, and food labels offer one appropriate vehicle for this dissemination."

Soon, many claims appeared on foods—often only partly meeting FDA's proposed

criteria. For this reason and because of widely divergent comments on the proposal, FDA solicited additional comments and held a public hearing. The agency withdrew the 1987 proposal and repropoed regulations in February 1990 to more narrowly define health claims and more clearly state its criteria for claims.

Scientific support for diet-disease relationships and public interest in health continued to grow, encouraging Congress in the fall of 1990 to pass the Nutrition Labeling and Education Act. The new law confirmed FDA's authority to regulate health claims on food. Among other things, it required that the agency determine whether health claims were appropriate for 10 relationships:

- calcium and osteoporosis
- sodium and hypertension
- lipids (fats and fat-like substances) and cardiovascular (heart and blood vessel) disease
- lipids and cancer
- dietary fiber and cardiovascular disease
- dietary fiber and cancer
- folic acid and neural tube defects
- antioxidant vitamins and cancer (antioxidants inhibit or prevent oxidation—a chemical reaction whose effect in the body is not well-understood)
- zinc and immune function in the elderly
- omega-3 fatty acids and heart disease.

FDA evaluated the scientific evidence and published its tentative findings in the Nov. 27, 1991, *Federal Register* food labeling proposal. The health claims proposals garnered more than 6,000 letters. To reach its final decisions about health claims, FDA reviewed more than 1,400 scientific studies and authoritative reports.

Definitions, Restrictions

According to the final rule, a "health claim" is any claim on the package label or other labeling (such as an ad) of a food, including fish and game meats, that characterizes the relationship of any nutrient or other substance in the food to a disease or health-related condition.

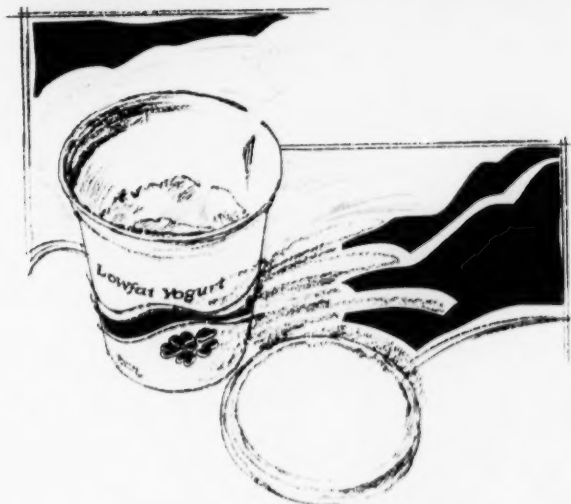
An example of a health claim is, "Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers." This claim associates the two necessary components: a specific nutrient or food substance and a specific health problem.

Health claims include implied claims, which indirectly assert a relationship. Implied claims may appear as third-party references, such as "The National Cancer Institute recommends a high-fiber diet." Brand names (such as "Heart Smart"), symbols (such as heart-shaped logos), and vignettes (descriptions), when used with specific nutrient information, may within the context of the label result in a health claim.

In contrast, claims about general health or food classes are not health claims. Some examples: the Food Guide Pyramid logo (a pyramid-shaped depiction of the Dietary Guidelines for Americans), valentine candy in a heart-shaped box, and "Eat five servings of fruits and vegetables a day for good health." FDA would consider those examples health claims if a specific nutrient and disease were introduced—the term "low fat" and a heart logo, for instance. Context is the key.

The definition does not cover nutrient-deficiency diseases—such as scurvy, caused by lack of vitamin C. Such dis-

Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.



eases, which are no longer of major public health significance in the United States, are adequately regulated under other portions of the FD&C Act. Thus, FDA believes it would be inappropriate to subject these relationships to the health claims rules.

Finally, health claims do not apply to:

- exempt infant formulas
- foods intended for children under 2 years
- medical foods, which are foods formulated for dietary management of diseases or other medical conditions
- foods regulated as drugs.

To qualify for labeling with a health claim, foods must contain:

- a nutrient (such as calcium) whose consumption at a specified level as part of an appropriate diet will have a positive effect on the risk of disease **or**
- a nutrient of concern (such as fat) below a specified level.

The foods must contribute nutrition to the diet by containing at least 10 percent of the Daily Value (DV) of one or more of the nutrients vitamin A, vitamin C, iron, calcium, protein, and fiber. These nutrients must occur naturally in the food at least at 10 percent of the DV.

The Nutrition Labeling and Education Act specifies that foods bearing health claims must not contain any nutrient or food substance in an amount that increases the risk of a disease or health condition. Because dietary guidance calls for people to limit intake of fat, saturated fat, cholesterol, and sodium, FDA identified these substances as risk nutrients and set disqualifying levels for them per serving and per reference amount and, when a food

has a small reference amount (30 grams or two tablespoons or less), per 50 g of the food. (As stated in FDA's new rule, the "reference amount" is the amount customarily consumed on an eating occasion. The serving size will be close, but not necessarily identical, to the reference amount.) Foods bearing health claims, then, must contain 20 percent or less of the DV of: fat (13 g), saturated fat (4 g), cholesterol (60 milligrams), and sodium (480 mg).

Thus, whole milk, which is high in calcium, may not bear a calcium-osteoporosis claim because its fat content exceeds the disqualifying levels, and excess fat increases the risk of cancer and heart disease. Skim, 1 percent, and 2 percent milks and milk products generally qualify for calcium-osteoporosis health claims.

Main dish products (6 ounces or more with not less than 40 g of two foods from two or more of the four food groups) and meal products (10 ounces or more with not less than 40 g of three or more foods from two or more food groups) may not bear claims if they contain, respectively, 30 or 40 percent or more of the DV for a disqualifying nutrient. FDA may by regulation permit a claim on food that contains a nutrient in amounts that exceed the disqualifying level if the agency finds that the claim will help consumers maintain a healthy diet, and the labeling discloses the presence of the nutrient at that level. No such exceptions have yet been made.

Every statement, phrase or symbol on a food label (health claim or not) must be truthful and not misleading. Because many factors affect disease development, it would be misleading to overemphasize the role of the food substance in a claim, such

as indicating it will prevent the disease. Claims that a substance will prevent a disease are drug claims. Thus, in discussing the diet-disease relationship, health claims may only say the substance "may" or "might" reduce the risk. Claims must indicate the disease depends on many factors and may be required to mention other factors that affect the benefit—such as regular exercise, in calcium-osteoporosis claims.

Health claims cannot substitute a disease risk indicator for the disease itself, unless authorized. Claims for fat and heart disease, for instance, may optionally include the link of lowering blood cholesterol—as in, "Development of heart disease depends upon many factors. A healthful diet low in saturated fat and cholesterol may lower blood cholesterol levels and may reduce the risk of heart disease."

Many claims will be consistent with certain recognized dietary guidelines and may state them. A sodium-hypertension health claim, for instance, may say it is consistent with dietary guidelines to "use salt and sodium in moderation." Some other optional information is allowed, such as the number of people affected by the disease.

New Claims

When petitioned, FDA will authorize new claims if specific requirements are met.

First, the nutrient or food substance must be related to a disease or health condition for which most people or a specific group of people, such as the elderly, are at risk.

Second, for a claim to be valid, the rules
(Continued on page 27)

Claim Specifics

Nutrient/Food– Disease Link

Calcium and osteoporosis:

Low calcium intake is one risk factor for osteoporosis, a condition of lowered bone mass, or density. Lifelong adequate calcium intake helps maintain bone health by increasing as much as genetically possible the amount of bone formed in the teens and early adult life and by helping to slow the rate of bone loss that occurs later in life.

Sodium and hypertension (high blood pressure):

Hypertension is a risk factor for coronary heart disease and stroke deaths. The most common source of sodium is table salt. Diets low in sodium may help lower blood pressure and related risks in many people. Guidelines recommend daily sodium intakes of not more than 2,400 mg. Typical U.S. intakes are 3,000 to 6,000 mg.

Typical Foods

Low-fat and skim milks, yogurts, tofu, calcium-fortified citrus drinks, and some calcium supplements.

Unsalted tuna, salmon, fruits and vegetables, and low-fat milks, low-fat yogurts, cottage cheeses, sherbets, ice milk, cereal, flour, and pastas (not egg pastas).

Requirements

Food or supplement must be “high” in calcium; must not contain more phosphorus than calcium. Claims must cite other risk factors; state the need for regular exercise and a healthful diet; explain that adequate calcium early in life helps reduce fracture risk later by increasing as much as genetically possible a person’s peak bone mass; and indicate that those at greatest risk of developing osteoporosis later in life are white and Asian teenage and young adult women, who are in their bone-forming years. Claims for products with more than 400 mg of calcium per day must state that a daily intake over 2,000 mg offers no added known benefit to bone health.

Foods must meet criteria for “low sodium” Claims must use “sodium” and “high blood pressure” in discussing the nutrient-disease link.

Sample Claim

“Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.”

“Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.”

Dietary fat and cancer:

Diets high in fat increase the risk of some types of cancer, such as cancers of the breast, colon and prostate. While scientists don't know how total fat intake affects cancer development, low-fat diets reduce the risk. Experts recommend that Americans consume 30 percent or less of daily calories as fat. Typical U.S. intakes are 37 percent.

Dietary saturated fat and cholesterol and risk of coronary heart disease:

Diets high in saturated fat and cholesterol increase total and low-density (bad) blood cholesterol levels and, thus, the risk of coronary heart disease. Diets low in saturated fat and cholesterol decrease the risk. Guidelines recommend that American diets contain less than 10 percent of calories from saturated fat and less than 300 mg cholesterol daily. The average American adult diet has 13 percent saturated fat and 300 to 400 mg cholesterol a day.

Fiber-containing grain products, fruits, and vegetables and cancer:

Diets low in fat and rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer. The exact role of total dietary fiber, fiber components, and other nutrients and substances in these foods is not fully understood.

Fruits, vegetables, reduced-fat milk products, cereals, pastas, flours, and sherbets.

Fruits, vegetables, skim and low-fat milks, cereals, whole-grain products, and pastas (not egg pastas).

Whole-grain breads and cereals, fruits, and vegetables.

Foods must meet criteria for "low fat." Fish and game meats must meet criteria for "extra lean." Claims may not mention specific types of fats and must use "total fat" or "fat" and "some types of cancer" or "some cancers" in discussing the nutrient-disease link.

Foods must meet criteria for "low saturated fat," "low cholesterol," and "low fat." Fish and game meats must meet criteria for "extra lean." Claims must use "saturated fat and cholesterol" and "coronary heart disease" or "heart disease" in discussing the nutrient-disease link.

Foods must meet criteria for "low fat" and, without fortification, be a "good source" of dietary fiber. Claims must not specify types of fiber and must use "fiber," "dietary fiber," or "total dietary fiber" and "some types of cancer" or "some cancers" in discussing the nutrient-disease link.

"Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers."

"While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease."

"Low-fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors."

Claim Specifics

Nutrient/Food– Disease Link

Fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease:

Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, may reduce the risk of coronary heart disease. (It is impossible to adequately distinguish the effects of fiber, including soluble fiber, from those of other food components.)

Fruits and vegetables and cancer:

Diets low in fat and rich in fruits and vegetables may reduce the risk of some cancers. Fruits and vegetables are low-fat foods and may contain fiber or vitamin A (as beta-carotene) and vitamin C. (The effects of these vitamins cannot be adequately distinguished from those of other fruit or vegetable components.)

Typical Foods

Fruits, vegetables, and whole-grain breads and cereals.

Fruits and vegetables.

Requirements

Foods must meet criteria for “low saturated fat,” “low fat,” and “low cholesterol.” They must contain, without fortification, at least 0.6 g of soluble fiber per reference amount, and the soluble fiber content must be listed. Claims must use “fiber,” “dietary fiber,” “some types of dietary fiber,” “some dietary fibers,” or “some fibers” and “coronary heart disease” or “heart disease” in discussing the nutrient-disease link. The term “soluble fiber” may be added.

Foods must meet criteria for “low fat” and, without fortification, be a “good source” of fiber, vitamin A, or vitamin C. Claims must characterize fruits and vegetables as foods that are low in fat and may contain dietary fiber, vitamin A, or vitamin C; characterize the food itself as a “good source” of one or more of these nutrients, which must be listed; refrain from specifying types of fatty acids; and use “total fat” or “fat,” “some types of cancer” or “some cancers,” and “fiber,” “dietary fiber,” or “total dietary fiber” in discussing the nutrient-disease link.

Sample Claim

“Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.”

“Low-fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, or vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.”

About Supplements . . .

The Dietary Supplement Act, Title II of the Prescription Drug User Fee Act of 1992, prohibits FDA until at least Dec. 15, 1993, from making final labeling rules for supplements and from taking action against supplements for unauthorized health claims. The legislation became law Oct. 30, 1992.

As with conventional food, however, a supplement component may qualify for a health claim under the Nutrition Labeling and Education Act of 1990 if it confers a health benefit due to its nutritive value and meets other FDA health claims criteria.

"If a nutrient is shown to provide the benefit, then it's the nutrient content that's important, not its source," says Elizabeth Yetley, Ph.D., of FDA's Center for Food Safety and Applied Nutrition, who coordinated the agency's review of health claims.

Dietary supplements include products providing nutrition, such as vitamins, minerals, amino acids, and fatty acids. They also include substances such as herbs and bee pollen.

Under the Nutrition Labeling and Education Act, even when a supplement contains a nutrient in an amount in excess of that found in conventional food, the rule doesn't necessarily prevent a health claim. For example, a calcium-osteoporosis health claim would be permitted in supplements containing calcium in higher potencies than those found naturally in foods such as dairy products, provided the supplement meets the claim's other criteria. If the potency exceeds 400 milligrams a day, however, the labeling must state there's no known benefit from taking more than 2,000 mg a day.

Meanwhile, the new supplements act requires that, during 1993, the General Accounting Office study FDA's management of dietary supplements, and the Office of Technology Assessment study the relationship between supplements regulation (in other countries as well as the United States) and health outcomes. Under the act, FDA is to publish proposed rules (by June 15) and final rules (by Dec. 31, but no earlier than Dec. 15) that are responsive to the Nutrition Labeling and Education Act regarding supplements. ■

(Continued from page 23)

require significant agreement among qualified experts that the claim is supported by the "totality of publicly available scientific evidence." This evidence must include data from well-designed studies conducted with recognized scientific procedures and principles.

OTC Drugs with Food Health Claims

Over-the-counter drugs that are also foods present complicating concerns for FDA. One such case is calcium antacids, which have been used as dietary supplements as well.

As drugs, such products are labeled for short-term problems, which, if persistent, may indicate a more serious condition, such as an underlying ulcer. Consequently, the drug labeling directs users to see a doctor if symptoms persist. As food supplements, however, these products are labeled for long-term use at lower levels consistent with daily dietary guidelines. The labeling usually provides no directions to seek medical help and places no time limits on use.

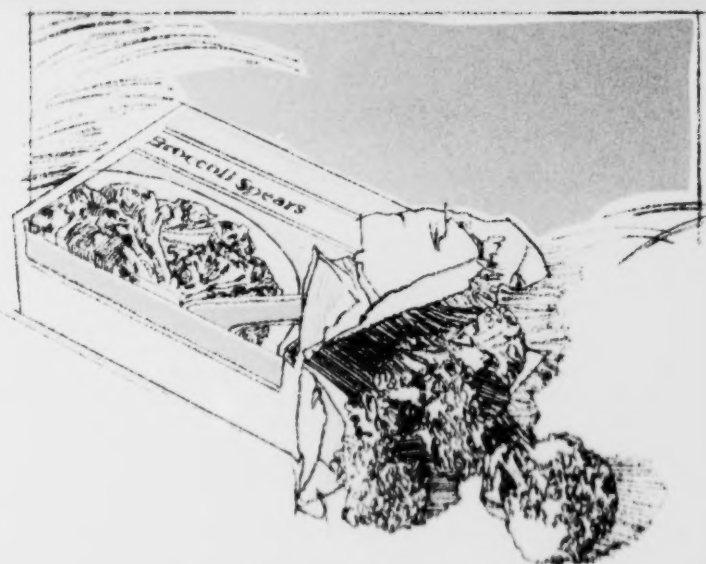
Even though the label may separate such dual directions, FDA is concerned a person may incorrectly assume the medical dosage is safe for dietary usage.

"If firms want to market products with both food and drug instructions or with health claims," says FDA's Yetley, "they may need to provide data to show the agency that the labeling won't confuse consumers, that consumers can differentiate between drug instructions and food or health claim instructions, and that, therefore, the product won't be misused."

Guidelines for Using Health Claims

In labeling with approved health claims, all statements about the diet-disease relationship must be consistent with FDA con-

While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease.



clusions. Claims must enable consumers to understand the relationship and the nutrient or food substance's importance in the relationship in terms of a total daily diet.

Required information must be of one type size and in one place, without intervening material. The main panel may refer to a claim located elsewhere, as in an attached pamphlet.

When a health-claim graphic, such as a heart symbol, is used, the claim or a reference to its location must be nearby.

The food label must list the content of the nutrient for which a health claim is made.

If a claim is about reduced levels of a nutrient, such as cholesterol, the content must be low enough to qualify for the approved claim or must meet the FDA definition for "low."

If a claim is made about a nutrient at increased levels, the content must be in an appropriate form and high enough to justify the claim. If a definition exists for the nutrient, the content must meet that definition's "high," unless the approved health claim specifies an alternative level.

Denied Claims

FDA denied a claim for omega-3 fatty acids in reducing the risk of coronary heart disease. Omega-3s are found in oily fish and sea mammals. John Wallingford, Ph.D., who led FDA's review of this claim, noted, "Results of studies relating fish intake and risk of coronary heart disease were conflicting and inconsistent. The most compelling evidence was a well-controlled study that showed fish con-

sumption may reduce the chance of death from a second heart attack. However, these studies did not establish that the effects were due specifically to omega-3 fatty acids."

Data revealed that omega-3s may raise the blood LDL-cholesterol (the bad type) of people with high blood fats and may interfere with blood glucose control in diabetics.

FDA also denied a claim about zinc (an essential trace mineral) and immune function in the elderly. Some studies had suggested that older people consume less zinc than recommended and that intake declines as people age. FDA concluded the evidence did not support the theory that increased dietary zinc would improve the immune function in older Americans.

Some studies appeared to show zinc supplements improved immunity to disease in older people. But the number of study participants was limited, many studies were flawed, and reported improvements were small. In larger, well-designed studies in which older patients received either zinc or placebos (inert pills) in addition to multi-vitamin and mineral preparations, the greatest immune function improvements were among those taking placebos. Zinc supplementation not only did not improve immune system function in the elderly, at 100 mg or more a day, it actually suppressed immunity.

FDA denied a claim for folic acid and neural tube birth defects. The agency continues, however, to consider this issue. Neural tube defects occur within the first six weeks after conception, often before the pregnancy is known. Adequate daily

folic acid intake (at least 0.4 mg, or 400 micrograms, but not more than 1 mg) has been recommended for women from puberty through menopause to reduce the risks of having a baby with these severe birth defects.

The agency convened an advisory committee of outside experts to resolve the remaining issues. "We are proceeding as quickly as possible to evaluate several potential safety issues," Yetley explains. "We don't want to have a health claim if it might cause harm."

FDA denied claims for fiber and cancer, fiber and cardiovascular disease, and antioxidant vitamins and cancer because the scientific evidence was inconclusive. It is impossible to adequately distinguish effects of fiber or antioxidants from those of other food components, the agency said.

Nevertheless, in approving the claim for fruits and vegetables and cancer, FDA incorporated information on vitamin A (as beta-carotene) and vitamin C. These nutrients are found in fruits and vegetables whose use as part of total dietary patterns is associated with reduced cancer risks.

As stated in the 1991 proposal, FDA considers a health claim on a food label "a promise to consumers that including the food in a diet . . . will be helpful in attaining the claimed benefit and will not introduce a risk of another disease or health-related condition." ■

Dixie Farley is a staff writer for FDA Consumer. Ellen Anderson, Ph.D., a research chemist in FDA's Center for Food Safety and Applied Nutrition, also contributed to this article.

A Little 'Lite' Reading

by Dori Stehlin

"Low fat." "No cholesterol."
"High in oat bran." "Light."
And don't forget "lite."

Until now, many of these claims have been nothing more than advertising hype. The public has been misled with products like the "light" vegetable oil that was just light in color and the "lite" cheesecake that was just light in texture.

But with the publication of new food labeling regulations in January 1993, the Food and Drug Administration and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) address the problem of misleading nutrition claims and help reestablish the credibility of the food label. The regulations spell out which nutrient content claims are allowed and under what circumstances they can be used.

There are 11 core terms:

- free
- low
- lean
- extra lean
- high
- good source
- reduced
- less
- light
- fewer
- more

Let Freedom Ring

The new regulations allow manufacturers the option to use the following synonyms for the term "free":

- without
- trivial source of
- negligible source of
- dietarily insignificant source of
- no
- zero

Whatever term the manufacturer chooses, the product must either be absolutely free of the nutrient in question or, if the nutrient is in the food, the amount must be dietetically trivial or physiologically insignificant.

For example, zero fat cannot be required because it is impossible to measure below a certain amount. So, the regulation will allow a fat-free claim on foods with less than 0.5 grams (g) of fat per serving, an amount that is physiologically insignificant even if a person eats several servings.

Foods that don't contain a certain nutrient naturally must be labeled to indicate that all foods of that type meet the claim. For example, a fat-free claim on applesauce would have to read "applesauce, a fat-free food."

"Free" also can be used in reference to saturated fat, cholesterol, sodium, sugars, and calories.

The Lowdown

A food meets the definition for "low" if a person can eat a large amount of the food without exceeding the Daily Value for the nutrient. (See "'Daily Values' Encourage Healthy Diet" on page 40.)

The synonyms allowed for "low" are:

- little
- few
- contains a small amount of
- low source of

"Low" claims can be made in reference to total fat, saturated fat, cholesterol, sodium, and calories.

A claim of "very low" can be made only about sodium.

Lean, Mean Eating Machine

"Lean" and "extra lean" can be used to describe the fat content of meat, poultry,

seafood, and game meats. (FSIS regulates meat and poultry products; FDA oversees seafood and game meats.)

"Lean" means the food has less than 10 g of fat, less than 4 g of saturated fat, and less than 95 milligrams (mg) of cholesterol per serving and per 100 g. An example of a serving is 55 g (2 oz.) for fish, shellfish or game meat. Some "lean" foods are Spanish mackerel, bluefin tuna, and domesticated rabbit.

"Extra lean" means the food has less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per serving and per 100 g. Examples of "extra lean" foods are haddock, swordfish, clams, and deer.

Percent Fat Free

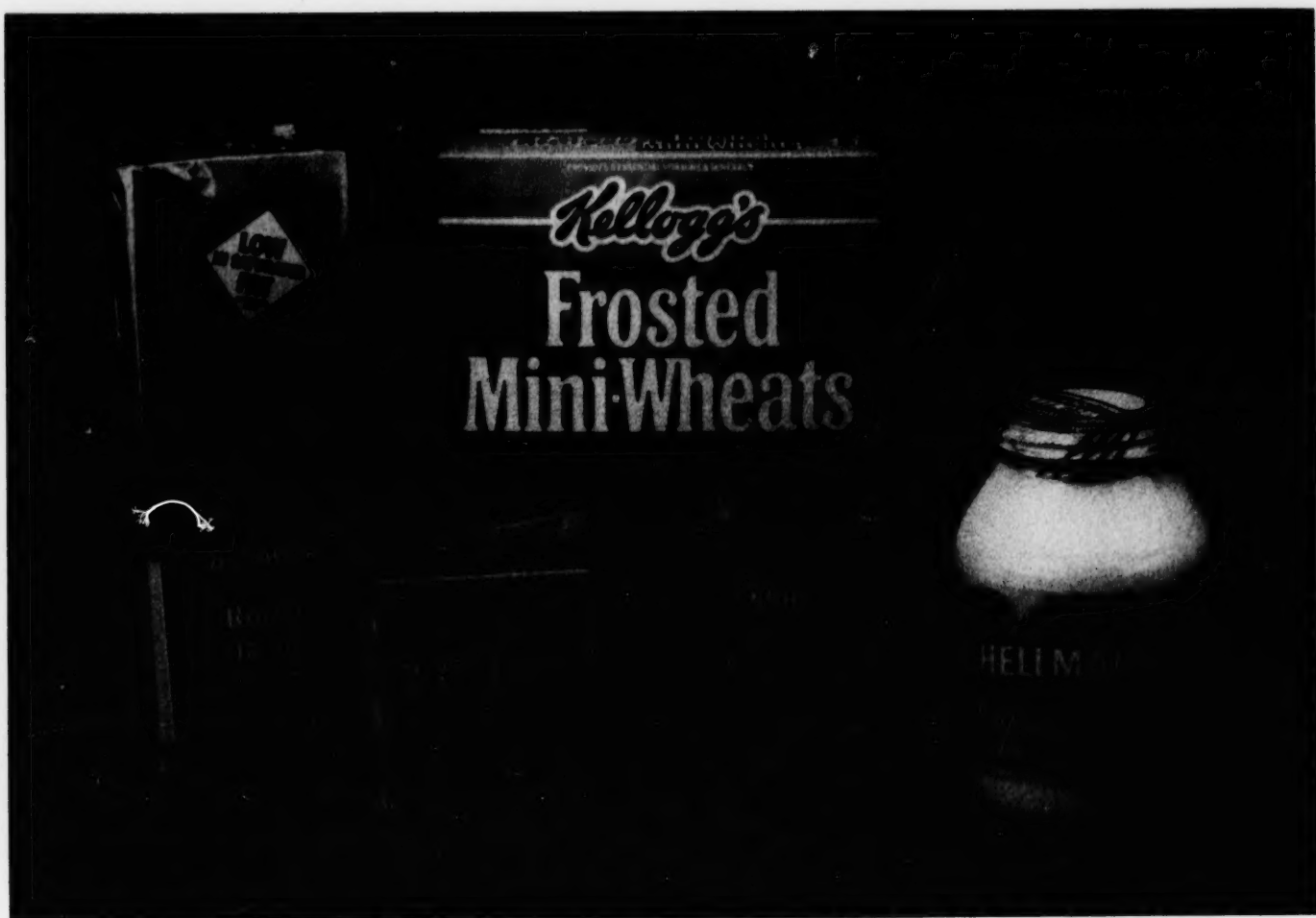
FDA and FSIS believe that this claim implies, and consumers expect, that products bearing "percent fat free" claims contain relatively small amounts of fat and are useful in maintaining a low-fat diet. Therefore, products with these claims must meet the definitions for low fat.

In addition, the claim must accurately reflect the amount of fat present in 100 g of the food. For example, if a food contains 2.5 g of fat per 50 g, the claim must be "95 percent fat free."

Take the High Road

"High" and "good source" focus on nutrients for which higher levels are desirable. To qualify for the "high" claim, the food must contain 20 percent or more of the Daily Value for that nutrient in a serving. Approved synonyms for high are "rich in" or "excellent source."

"Good source" means a serving contains 10 to 19 percent of the Daily Value for the nutrient.



By 1994, claims about the nutrient content of a food, such as "low cholesterol," "light," and others on these food packages, will have to mean the same on every product on which they appear.

Special Situations

"Standards of identity" define a food's composition and specify the ingredients it must contain. The government originally developed these standards to protect consumers from economic deception.

But some standards of identity require high amounts of nutrients that many consumers would like to avoid. For example, the standard for sour cream requires that the food contain 18 percent fat and the standard for mozzarella cheese requires it to be 45 percent fat. Before the new regulations, "reduced-fat" sour cream or mozzarella cheese were required to have their

own standards of identity or be called "imitation" or "substitute," names that consumers may perceive as negative.

The new regulations allow manufacturers to reduce the fat content of such products and call them "low fat" or "light," as appropriate, as long as the food is still nutritionally equivalent to the regular version. For example, sour cream can be called "light" as long as its fat content is reduced to 9 percent and it has vitamin A added to replace the amount lost when the fat was removed. If the company decides not to add the vitamin A, it must call the product "imitation light sour cream."

FDA is not allowing nutrient content claims on foods for infants and children

under 2, unless explicit permission has been given.

FDA allows manufacturers to use the terms "unsweetened" and "unsalted" on these foods because these claims are considered to be about taste rather than nutrient content. However, current dietary guidelines do not call for limiting salt or sugar in the diets of children under 2. Therefore, FDA will not allow phrases that imply low or reduced amounts of sodium and calories, such as "no salt added" and "no sugar added," on these types of foods. ■

—D.S.

Comparison Claims

Manufacturers who want to compare a nutritionally altered product with the regular product may make a relative claim—that is, "reduced," "less," "fewer," "more," or "light." The regular products, or reference foods, may be either an individual food or a group of foods representative of the type of food—for example, an average of three market leaders.

Restrictions on these claims and the reference foods include:

- A relative claim must include the percent difference and the identity of the reference food.
- "Reduced," "less" and "light" claims can't be made on products whose nutrient level in the reference food already meets the requirement for a "low" claim.
- Reference foods for "light" and "reduced" claims must be similar to the product bearing the claim—for example, reduced fat potato chips compared with regular potato chips.
- Reference foods for "less" and, in the

case of calories, "fewer" may use dissimilar products within a product category—for example, pretzels with 25 percent less fat than potato chips.

At the other end of the spectrum, a serving of a food carrying a "more" claim (or claims of fortified, enriched or added) must have at least 10 percent more of the Daily Value for a particular nutrient (that is, dietary fiber, potassium, protein, or an essential vitamin or mineral) than the reference food that it resembles.

Let There Be Light/Lite

"Light" or "lite" can mean one of two things:

First, that a nutritionally altered product contains one-third fewer calories or half the fat of the reference food. If the food derives 50 percent or more of its calories from fat, the reduction must be 50 percent of the fat.

Second, that the sodium content of a low-calorie, low-fat food has been reduced by 50 percent.

The term "light in sodium" is allowed if the food has at least 50 percent less sodium than a reference food. If the food still does not meet the definition for "low sodium," the label must include the disclaimer "not a low-sodium food."

"Light" will be allowed to describe color or texture, provided qualifying information is included. However, names that have a long history of use, such as "light brown sugar," can still be used without qualifying information.

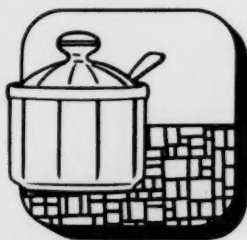
Meals and Main Dishes

Any product represented as or in a form commonly understood to be breakfast, lunch or dinner is subject to the special rules for meal products. Examples include frozen dinners, some pizzas, and shelf-stable items.

Under FDA rules, a main dish must weigh at least 6 ounces and contain at least two different foods from at least two of four specified food groups. (While FDA endorses the five food groups rec-

Getting Specific

Here are examples of the meanings of some descriptive words for specific nutrients:



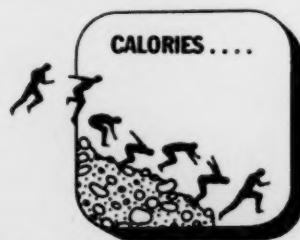
Sugar

Sugar free: less than 0.5 grams (g) per serving

No added sugar, Without added sugar, No sugar added:

- No sugars added during processing or packing, including ingredients that contain sugars (for example, fruit juices, apple-sauce, or dried fruit).
- Processing does not increase the sugar content above the amount naturally present in the ingredients. (A functionally insignificant increase in sugars is acceptable from processes used for purposes other than increasing sugar content.)
- The food that it resembles and for which it substitutes normally contains added sugars.
- If the food doesn't meet the requirements for a low- or reduced-calorie food, the product bears a statement that the food is not low-calorie or calorie-reduced and directs consumers' attention to the nutrition panel for further information on sugars and calorie content.

Reduced sugar: at least 25 percent less sugar per serving than reference food



Calories

Calorie free: fewer than 5 calories per serving

Low calorie: 40 calories or less per serving and if the serving is 30 g or less or 2 tablespoons or less, per 50 g of the food

Reduced or Fewer calories: at least 25 percent fewer calories per serving than reference food



Fat

Fat free: less than 0.5 g of fat per serving

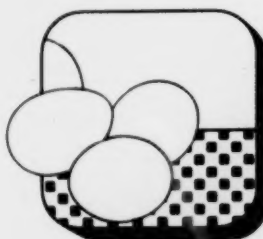
Saturated fat free: less than 0.5 g per serving and the level of trans fatty acids does not exceed 1 percent of total fat

Low fat: 3 g or less per serving, and if the serving is 30 g or less or 2 tablespoons or less, per 50 g of the food

Low saturated fat: 1 g or less per serving and not more than 15 percent of calories from saturated fatty acids

Reduced or Less fat: at least 25 percent less per serving than reference food

Reduced or Less saturated fat: at least 25 percent less per serving than reference food



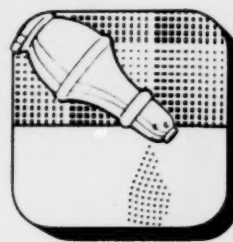
Cholesterol

Cholesterol free: less than 2 milligrams (mg) of cholesterol and 2 g or less of saturated fat per serving

Low cholesterol: 20 mg or less and 2 g or less of saturated fat per serving and, if the

serving is 30 g or less or 2 tablespoons or less, per 50 g of the food

Reduced or Less cholesterol: at least 25 percent less and 2 g or less of saturated fat per serving than reference food



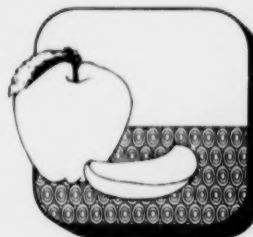
Sodium

Sodium free: less than 5 mg per serving

Low sodium: 140 mg or less per serving and, if the serving is 30 g or less or 2 tablespoons or less, per 50 g of the food

Very low sodium: 35 mg or less per serving and, if the serving is 30 g or less or 2 tablespoons or less, per 50 g of the food

Reduced or Less sodium: at least 25 percent less per serving than reference food



Fiber

High fiber: 5 g or more per serving. (Foods making high-fiber claims must meet the definition for low fat, or the level of total fat must appear next to the high-fiber claim.)

Good source of fiber: 2.5 g to 4.9 g per serving

More or Added fiber: at least 2.5 g more per serving than reference food

A serving of a food carrying a "more" claim (or claims of fortified, enriched or added) must have at least 10 percent more of the Daily Value for a particular nutrient (that is, dietary fiber, potassium, protein, or an essential vitamin or mineral) than the reference food that it resembles.

ommended in current dietary guidelines, the agency believes treating fruits and vegetables as separate groups in this situation would allow the inappropriate classification of a fruit and a vegetable product as a main dish.)

FDA requires a "meal" to weigh at least 10 ounces and have at least three different foods from at least two of the four specified food groups.

USDA defines a meal-type product as one weighing between 6 and 12 ounces per serving and containing ingredients from two or more of four specified food groups.

Claims that a meal or main dish is "free" of a nutrient, such as sodium or cholesterol, must meet the same requirements as those for individual foods.

"Low" claims can be made if the main dish or meal has:

- 120 calories or less per 100 g
- 140 mg sodium or less per 100 g
- 3 g fat or less and no more than 30 percent of calories from fat per 100 g
- 1 g saturated fat or less and no more than 10 percent calories from saturated fat per 100 g or
- 20 mg cholesterol or less per 100 g and no more than 2 g of saturated fat per 100 g.

Implied Claims

"Made with oat bran" and "no tropical oils" are examples of statements that may be implied nutrient content claims. Such claims are prohibited when they wrongfully imply that a food contains or does not contain a meaningful level of a nutrient. They are allowed if the food's nutrient content meets the definition for appropriate nutrient content descriptors that are im-

plied by the claim.

For example, FDA considers statements about some types of oil as an ingredient, such as "made with canola oil" or "contains corn oil," to imply that the oil in the product is low in saturated fat. Therefore, to carry that claim, a food would have to meet the definition of "low saturated fat."

The statement "made only with vegetable oil" implies that because vegetable oil is used instead of animal fat, the oil component contributes no cholesterol and is low in saturated fat. In this case, the claim could be used only if the food meets the definition of "cholesterol free" and "low saturated fat."

And the statement "contains no oil" implies that the product contains no fat and thus is fat free. Such a claim on a product that contained another source of fat, such as animal fat, would be misleading. Therefore, this statement would be allowed only if the food is truly fat free.

Claims that imply a product contains a particular amount of fiber, such as "high in oat bran," can be made only if the food actually meets the definition for "high" fiber or "good source" of fiber, whichever is appropriate.

Statements that don't fall under the rules for nutrient content implied claims and therefore are still allowed are:

- those that help consumers avoid certain foods because of religious beliefs or dietary practices—for example, a "milk-free" claim
- those about nonnutritive ingredients, such as "no preservatives" or "no artificial colors"
- those about ingredients that provide added value, such as "contains real fruit"

- statements of identity, such as "Colombian coffee" and "100 percent corn oil"

Fresh

Although not mandated by the Nutrition Labeling and Education Act of 1990, as regulations for the other nutrient content claims are, FDA has issued a regulation for the term "fresh." Under this regulation, "fresh" can be used only on a food that is raw, has never been frozen or heated, and contains no preservatives. (Irradiation at low levels is allowed.) "Fresh frozen," "frozen fresh," and "freshly frozen" can be used for foods that are quickly frozen while still fresh. Blanching (brief scalding before freezing to prevent nutrient breakdown) is allowed.

Other uses of the term "fresh," such as in "fresh milk" or "freshly baked bread," are not affected.

Healthy

Along with the final rule on nutrient content claims published last January, FDA and FSIS published proposed rules that would allow manufacturers to make a "healthy" claim on the label. Under FDA's proposal, "healthy" could be used if the food is low in fat and saturated fat and a serving does not contain more than 480 mg of sodium or more than 60 mg of cholesterol. USDA's proposal would allow the term if the food meets the definition for "lean" and contains no more than 480 mg of sodium per serving.

Final rules are expected in 1993. ■

Dori Stehlin is a member of FDA's public affairs staff.

'NUTRITION FACTS'

To Help Consumers Eat Smart

by Paula Kurtzweil

Susan Thom, of Parma, Ohio, knows how important it is for people to know the number of calories from fat they eat each day.

As a registered dietitian, she counsels patients on the need to limit fat consumption to 30 percent or less of total daily calories. As a person with diabetes, and thus at increased risk for heart disease, she strives to do the same for herself.

But, in the past, obtaining that information from the food label has required some mathematical skill—namely, multiplying the total grams (g) of fat in a serving by 9, since 1 g of fat contains 9 calories.

"It does take time," Thom said. "But if you want to feed yourself well, you have to look at the label."

Help is on the way. For Thom and millions of other Americans who seek to restrict their fat intake to recommended levels, a new dietary component is being added to the food label—"calories from fat."

It's just one of many new items of diet-related information manufacturers are required to offer on their food products by 1994. There also will be information on saturated fat, cholesterol, dietary fiber, and other nutrients that relate to today's health concerns, such as heart disease, cancer, and other diseases linked, at least in part, to diet.

There will be more complete nutrient content information because almost all the required nutrients will have to be listed as a percent of the Daily Value. There will be more uniform serving sizes, too, which will make nutritional comparisons between foods easier. And, because nutrition labeling is now mandatory for almost all processed foods, there will be a lot more products with this important information.

"The new information is going to be very helpful for consumers," said Virginia Wilkening, a registered dietitian in FDA's Office of Food Labeling.

"Some of the nutrients—saturated fat and cholesterol—have been allowed on the label before but on a voluntary basis," she said. "Dietary fiber and sugars were not allowed in the nutrition label. With the new label, consumers will soon have information about these and other nutrients, which can help them choose their foods more wisely."

The new requirements for nutrition labeling are spelled out in regulations issued in January 1993 by FDA and the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS). FDA's regulations meet the provisions of the Nutrition Labeling and Education Act of 1990 (NLEA), which, among other things, re-

quires FDA to make nutrition labeling mandatory for almost all processed foods. FSIS' regulations, which cover meat and poultry products, largely parallel FDA's. (Meat and poultry products were not covered by NLEA.)

FDA has set May 8, 1994, as the date by which food manufacturers must comply with the new nutrition labeling regulations. FSIS requires meat and poultry processors to relabel their products by July 6, 1994. However, some newly labeled products may begin appearing in grocery stores much sooner than the deadlines.

Dietary Components

What can consumers expect? First, they will see a new name for the nutrition panel. It used to go by "Nutrition Information Per Serving." Now, it will be called "Nutrition Facts." That title will

Old Label

NUTRITION INFORMATION	PER SERVING
SERVING SIZE.....	5 OZ.
SERVINGS PER CONTAINER.....	4
CALORIES.....	250
PROTEIN.....	9g
CARBOHYDRATE.....	19g
FAT.....	11g
SODIUM.....	530mg

PERCENTAGE OF U.S. RECOMMENDED DAILY ALLOWANCES (U.S. RDA)

PROTEIN.....	10
VITAMIN A.....	*
VITAMIN C.....	*
THIAMINE.....	8
RIBOFLAVIN.....	15
NIACIN.....	2
CALCIUM.....	20
IRON.....	4

*CONTAINS LESS THAN 2% OF THE U.S. RDA OF THIS NUTRIENT

Starting this year, the 'old' nutrition label format above will be replaced by the one on the right. Both labels are for a frozen macaroni and cheese product.

Key Aspects of the New Nutrition Label

A number of consumer studies conducted by FDA, as well as outside groups, enabled FDA and the Food Safety and Inspection Service of the U.S. Department of Agriculture to agree on a new nutrition label. The new label is seen as offering the best opportunity to help consumers make informed food choices and to understand how a particular food fits into the total daily diet.

New heading signals a new label.

More consistent serving sizes, in both household and metric measures, replace those that used to be set by manufacturers.

Nutrients required on nutrition panel are those most important to the health of today's consumers, most of whom need to worry about getting too much of certain items (fat, for example), rather than too few vitamins or minerals, as in the past.

Conversion guide helps consumers learn caloric value of the energy-producing nutrients.

Nutrition Facts

Serving Size 1 cup (228g)

Servings Per Container 2

Amount Per Serving

Calories 260 **Calories from Fat** 120

% Daily Value*

Total Fat 13g **20%**

Saturated Fat 5g **25%**

Cholesterol 30mg **10%**

Sodium 660mg **28%**

Total Carbohydrate 31g **10%**

Dietary Fiber 0g **0%**

Sugars 5g

Protein 5g

Vitamin A 4% • Vitamin C 2%

Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

		Calories: 2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:

Fat 9 • Carbohydrate 4 • Protein 4

New mandatory component helps consumers meet dietary guidelines recommending no more than 30 percent of calories from fat.

%Daily Value shows how a food fits into the overall daily diet.

Reference values help consumers learn good diet basics. They can be adjusted, depending on a person's calorie needs.

Types of Labels

A tabular format label (top) is allowed on packages, such as this can of tuna, that have less than 40 square inches for nutrition labeling.

A simplified nutrition label (bottom), in which information about some nutrients otherwise required in nutrition labeling is omitted, will appear on labels of foods, such as this can of cola, that do not contain significant amounts of certain nutrients.



Nutrition Facts

Serv. Size 1/3 cup (56g)
Servings about 3
Calories 80
Fat Cal. 10

*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 1g	2%	Total Carb. 0g	0%
Sat. Fat 0g	0%	Fiber 0g	0%
Cholest. 10mg	3%	Sugars 0g	
Sodium 200mg	8%	Protein 17g	
Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%			



Nutrition Facts

Serving Size 1 can (360 mL)

Amount Per Serving

Calories 140

% Daily Value*

Total Fat 0g	0%
Sodium 20mg	1%
Total Carbohydrate 36g	12%
Sugars 36 g	
Protein 0g	0%

* Percent Daily Values are based on a 2,000 calorie diet.

signal to consumers that the product is newly labeled according to FDA and FSIS' new regulations.

The new panel will be built around a new set of dietary components. (See graphic, page 35.) The mandatory (underlined) and voluntary dietary components and order in which they must appear are:

- total calories
- calories from fat
- calories from saturated fat
- total fat
- saturated fat
- stearic acid (on meat and poultry products only)
- polyunsaturated fat
- monounsaturated fat
- cholesterol
- sodium
- potassium
- total carbohydrate
- dietary fiber
- soluble fiber
- insoluble fiber
- sugars
- sugar alcohol (for example, the sugar substitutes xylitol, mannitol and sorbitol)
- other carbohydrate (the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, if declared)
- protein
- vitamin A
- percent of vitamin A present as beta-carotene
- vitamin C
- calcium
- iron
- other essential vitamins and minerals.

If a food is fortified or enriched with any of the optional components, or if a claim is made about any of them, the pertinent nutrition information then becomes mandatory.

These mandatory and voluntary components are the only ones allowed on the nutrition panel. The listing of single amino

acids, maltodextrin, calories from polyunsaturated fat, and calories from carbohydrate, for example, may not appear on the label.

The reason, according to Wilkening, is to help consumers focus on nutrients of public health significance. "Too much additional information could clutter the label or mislead or confuse the consumer," she said.

Nutrients required on the label, she pointed out, reflect current public health concerns and coincide with current public health recommendations. She noted that the order in which the food components and nutrients are required to appear reflects their public health significance and the order in which they were specified in NLEA.

On the new food label, the listing of thiamin, riboflavin and niacin will not be mandatory. Under the old nutrition labeling program, these vitamins were required to be listed. But because deficiencies of these are no longer a public health problem in this country, listing them is now optional.

New Format

Consumers also will see a new format, one that calls for many of the macronutrients (such as fat, cholesterol, sodium, carbohydrate, and protein) to be declared as a percent of the Daily Value—a new label reference value. The amount, in grams or milligrams per serving, of these nutrients still must be listed to their immediate right. But, for the first time, a column headed "%Daily Value" will appear.

According to Wilkening, the percent declaration of the Daily Value offers an advantage over amount declaration: The percent Daily Values put the nutrients on an equal footing in the context of a total daily diet.

For example, she said, a food is low in sodium if it has less than 140 mg of so-

dium. "But people look at that number, 140, and think it's a tremendous amount, when it actually is less than 6 percent of the Daily Value."

On the other hand, she said, a food with 5 g of saturated fat could be construed as being low in that nutrient just because 5 is a small number. Actually, that food would provide one-fourth the total Daily Value of 20 g of saturated fat for a 2,000-calorie diet.

"People are affected by the size of numbers," she said. "That's why percentages are helpful. They put all of the nutrients on a level playing field."

The percent Daily Value listing will carry a footnote stating that the percentages are based on a 2,000-calorie diet and that a person's individual dietary goal is based on his or her calorie needs. Some nutrition labels—at least those on larger packages—will list daily values for selected nutrients for a 2,000- and a 2,500-calorie diet and the number of calories per gram of fat, carbohydrate and protein. The calorie conversion information is required as a general guide about the caloric contributions of fat, carbohydrate and protein.

The content of micronutrients—that is, vitamins and minerals—will continue to be expressed as a percent, although the term "Daily Value" will replace "U.S. Recommended Daily Allowance."

Modifications

Some foods will carry a variation of this format. For example, the label of foods for children under 2 (except infant formula, which is exempt from nutrition labeling under NLEA) will not carry information about calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol.

The reason, according to Wilkening, is to prevent parents from inadvertently assuming that infants and toddlers should restrict their fat intake, when in fact, they

should not. Fat is important during this life stage, she said, to ensure adequate growth and development.

The labels of food for children under 4 cannot include percentages of Daily Values for macronutrients, except protein, nor any footnote information, including the lists of Daily Values for selected nutrients. The reason: Other than protein, FDA has not established Daily Values for macronutrients for this age group. The percent Daily Values for vitamins and minerals is allowed, however. The content of the other nutrients must be expressed as an amount by weight in a separate column to the right of the macronutrients.

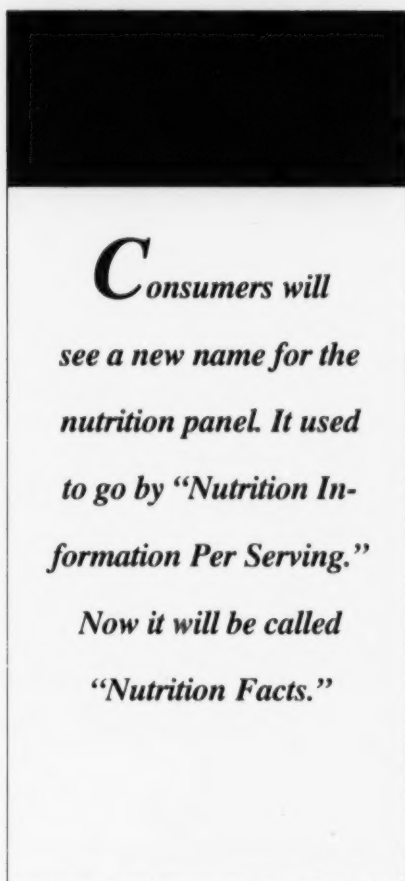
Other foods may qualify for a simplified label format. (See bottom label, page 36.) This format is allowed when the food contains insignificant amounts of seven or more of the mandatory dietary components, including total calories. "Insignificant" means that a declaration of "zero" could be made in nutrition labeling or, for total carbohydrate, dietary fiber, and protein, a declaration of "less than 1 g."

For foods for children under 2, the simplified format may be used if the product contains insignificant amounts of six or more of the following: calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamins A and C, calcium, and iron.

When the simplified format is used, information on total calories, total fat, total carbohydrate, protein, and sodium—even if they are present in insignificant amounts—must be listed. Calories from fat and other nutrients must be listed if they are present in more than insignificant amounts. Nutrients added to the food must be listed, too.

Serving Sizes

Whatever the format, the serving size remains the basis for reporting each nutrient's amount. However, unlike in the past, serving sizes now will be more uniform and closer to the amounts that many



Consumers will
see a new name for the
nutrition panel. It used
to go by "Nutrition In-
formation Per Serving."

Now it will be called
"Nutrition Facts."

people actually eat. They also must be expressed in both common household and metric measures. (See accompanying table.)

Before, the serving size was up to the discretion of the food manufacturer. As a result, said Youngmee Park, Ph.D., a nutritionist in FDA's Office of Special Nutritionals, serving sizes often varied widely, making it difficult for consumers to compare nutritional qualities of similar products or to determine the nutrient content of the amount of food they normally ate.

The uniformity also is important, she said, for giving consistency to health claims and words describing nutrient content, such as "high fiber" and "reduced fat."

FDA and FSIS define serving size as the amount of food customarily eaten at one time. It is based on FDA- and USDA-established lists of "Reference Amounts Customarily Consumed Per Eating Occasion."

These reference amounts, which are part of the new regulations, are broken down

into 139 FDA-regulated food product categories, including 11 groups of foods for children under 4, and 23 USDA meat and poultry product categories. They list the amounts of food customarily consumed per eating occasion for each food category, based primarily on national food consumption surveys. FDA's list also gives the suggested label statement for serving size declaration.

For example, the category "breads (excluding sweet quick type), rolls" has a reference amount of 50 g, and the appropriate label statement for sliced bread is "___ piece(s) ___ (g)" or, for unsliced bread, "2 oz (56 g/___ inch slice)."

The serving size of products that come in discrete units, such as cookies, candy bars, and sliced products, is the number of whole units that most closely approximates the reference amount. For example, cookies have a reference amount of 30 g. The household measure closest to that amount is the number of cookies that comes closest to weighing 30 g. Thus, the serving size on the label of a cookie package in which each cookie weighs 13 g would read "2 cookies (26 g)."

If one unit weighs more than 50 percent but less than 200 percent of the reference amount, the serving size is one unit. For example, the reference amount for bread is 50 g; therefore, the label of a loaf of bread in which each slice weighs more than 25 g would state that a serving size is one slice.

For food products packaged and sold individually, if an individual package is less than 200 percent of the applicable reference amount, the item qualifies as one serving. Thus, a 360-milliliter (mL) (12 fluid-ounce) can of soda is one serving because the reference amount for carbonated beverages is 240 mL (8 fluid ounces).

However, if the product has a reference amount of 100 g or 100 mL or more and the package contains more than 150 percent but less than 200 percent of the reference amount, manufacturers have the op-

Metric Conversion Chart

Units as they will appear for serving sizes on label

Household Measure	Metric Measure
1 tsp	5 mL
1 tbsp	15 mL
1 cup	240 mL
1 fl oz	30 mL
1 oz	28 g

tsp = teaspoon

tbsp = tablespoon

fl oz = fluid ounce

oz = ounce

mL = milliliter

g = gram

tion of deciding whether the product is one or two servings.

For example, the serving size reference amount for soup is 245 g. So a 15-ounce (420 g) can can be listed as either one or two servings.

Presentation

There also are rules governing how the nutrition information is displayed. Under existing FDA regulations, nutrition information must appear on the information panel to the immediate right of the principal panel. Thus, on boxed foods, for example, in which the principal panel is on the front of the box, the nutrition information appears on the right side of the box. Packages whose area to the immediate right is too small or not suited for such labeling may provide information on the next panel to the right.

FSIS allows nutrition information to be listed on the principal or information panels.

The new food labeling rules call for one additional variation: For packages that are 40 square inches or less, the nutrition information may be placed on any label panel.

The rules also address size and prominence of the typeface. For example, the heading "Nutrition Facts" must be set in the largest type on the nutrition panel and be highlighted in some manner, such as boldface, all capital letters, or another graphic to distinguish it from the other information. Such highlighting also is required for headings such as "Amount per serving" and "%Daily Value" and for the names of dietary components that are not subcomponents—that is, calories, total fat, cholesterol, sodium, total carbohydrate, and protein.

Exceptions and Exemptions

In some instances, special provisions exist for providing nutrition information. For example:

- Nutrition information about game meat, such as deer, bison, rabbit, quail, wild turkey, and ostrich, may be provided on

counter cards, signs, or other point-of-purchase materials. Because little nutrient data exists for these foods, FDA believes that allowing this option will enable game meat producers to give first priority to collecting appropriate data and make it easier for them to update the information as it becomes available.

- FDA-regulated food packages with less than 12 square inches available for nutrition labeling do not have to carry nutrition information. However, they must provide an address or telephone number for consumers to obtain the required nutrition information.
- Packages with less than 40 square inches for nutrition labeling may present nutrition information in a tabular format (see top label, page 36), abbreviate the names of dietary components, and omit the footnotes with the list of daily values and caloric conversion information but include a footnote stating that the percent

Daily Values are based on a 2,000-calorie diet or place nutrition information on other panels.

Some foods are exempt from nutrition labeling. These include:

- food produced by small businesses. (As mandated by NLEA, FDA defines a small business as one with food sales of less than \$50,000 a year or total sales of less than \$500,000. FSIS defines a small business as one employing 500 or fewer employees and producing no more than a certain amount of product per year.)
- food served for immediate consumption, such as that served in restaurants and hospital cafeterias, on airplanes, and by food service vendors (such as mall cookie counters, sidewalk vendors, and vending machines)
- ready-to-eat foods that are not for immediate consumption, as long as the food is primarily prepared on site—for example, many bakery, deli, and candy store items
- food shipped in bulk, as long as it is not for sale in that form to consumers
- medical foods
- plain coffee and tea, flavor extracts, food colors, some spices, and other foods that contain no significant amounts of any nutrients
- donated foods
- products intended for export
- individually wrapped FSIS-regulated products weighing less than half an ounce and making no nutrient content claims.

Although these foods are exempt, they are free to carry nutrition information, when appropriate—as long as it complies with the new regulations.

But, there will be plenty of other foods carrying the new nutrition information. Dietitian Susan Thom sees that as a plus.

"We'll all know exactly what we're putting in our mouths," she said. "So there'll be little room for excuses." ■

Paula Kurtzweil is a member of FDA's public affairs staff.

'DAILY VALUES'

Encourage Healthy Diet

by Paula Kurtzweil

If you haven't added "DV" to your vocabulary yet, you probably will before long.

It stands for Daily Value, a new dietary reference value to help consumers use food label information to plan a healthy overall diet.

DVs actually comprise two sets of reference values for nutrients: Daily Reference Values, or DRVs, and Reference Daily Intakes, or RDIs. But these two sets are "behind the scenes" in food labeling; only the Daily Value term will appear on the label to make label reading less confusing.

In fact, said Christine Lewis, Ph.D., a registered dietitian and director of the division of technical evaluation in FDA's Office of Food Labeling, the Daily Value term is the only one of the terms that will be used in the government's food labeling education campaign. "The DV term is the one we expect consumers and professionals to use," she said.

FDA-regulated products must begin using the Daily Value as the basis for declaring nutrient content by May 8, 1994. U.S. Department of Agriculture-regulated products—meat and poultry—have until July 6, 1994.

The move to Daily Values is due in large part to the Nutrition Labeling and Education Act of 1990. Among other things, the law requires nutrition label information to be conveyed in a way that en-

ables the public to observe and comprehend the information readily and to understand its relative significance in the context of a total daily diet.

According to Lewis, the DV does that in two ways: First, it serves as a basis for declaring on the label the percent of the Daily Value for each nutrient that a serving of the food provides.

For example, the Daily Value for fat, based on a 2,000-calorie diet, is 65 grams (g). A food that has 13 g of fat per serving would state on the label that the "percent Daily Value" for fat is 20 percent.

Second, it provides a basis for thresholds that define descriptive words for nutrient content, called descriptors, such as "high fiber" and "low fat." For example, the descriptor "high fiber" can be used if a serving of food provides 20 percent or more of the Daily Value for fiber—that is, 5 g or more.

What it is *not* intended to do is tell people what amounts of nutrients they should eat every day.

"They're not recommended intakes," Lewis said. "They're really just reference points to help people get some kind of perspective on what their overall daily dietary needs should be."

New References

Although they won't show up on the label, DRVs and RDIs have an important regulatory role. They serve as the basis for calculating percent Daily Values.

(Continued on page 43)



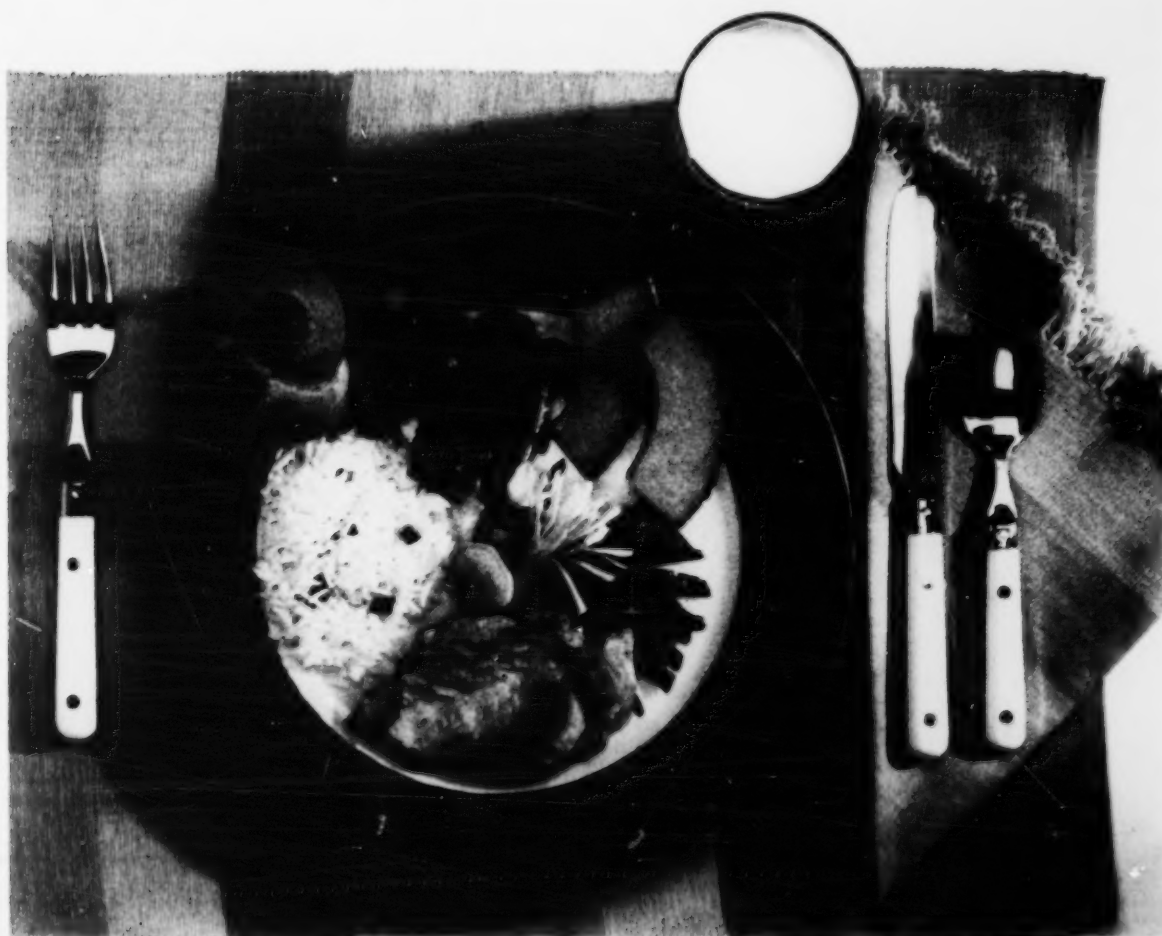
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*Daily Reference Values (DRVs)**

Food Component	DRV
fat	65 grams (g)
saturated fatty acids	20 g
cholesterol	300 milligrams (mg)
total carbohydrate	300 g
fiber	25 g
sodium	2,400 mg
potassium	3,500 mg
protein**	50 g

*Based on 2,000 calories a day for adults and children over 4 only

**DRV for protein does not apply to certain populations; Reference Daily Intake (RDI) for protein has been established for these groups: children 1 to 4 years: 16 g; infants under 1 year: 14 g; pregnant women: 60 g; nursing mothers: 65 g.



Reference Daily Intakes (RDIs)*

Nutrient	Amount
vitamin A	5,000 International Units (IU)
vitamin C	60 milligrams (mg)
thiamin	1.5 mg
riboflavin	1.7 mg
niacin	20 mg
calcium	1.0 gram (g)
iron	18 mg
vitamin D	400 IU
vitamin E	30 IU
vitamin B ₆	2.0 mg
folic acid	0.4 mg
vitamin B ₁₂	6 micrograms (mcg)
phosphorus	1.0 g
iodine	150 mcg
magnesium	400 mg
zinc	15 mg
copper	2 mg
biotin	0.3 mg
pantothenic acid	10 mg

*Based on National Academy of Sciences' 1968 Recommended Dietary Allowances.

(Continued from page 40)

DRVs are for nutrients for which no set of standards previously existed, such as fat and cholesterol. RDIs, on the other hand, replace the term "U.S. RDAs" (Recommended Daily Allowances), which were introduced in 1973 as a reference value for vitamins, minerals and protein in voluntary nutrition labeling. Despite the name change, the actual values (except the value for protein) will remain the same—at least for the time being. FDA will consider revising these values in the near future.

U.S. RDAs should not be confused with RDAs. The latter are short for Recommended *Dietary* Allowances, which are set by the National Academy of Sciences. FDA used the RDAs as the basis for setting U.S. RDAs (now called RDIs).

The confusion caused by the similarity of those terms was one of the reasons for the switch to RDI.

"The comments we received about the proposed name change generally agreed that there was a need to change the terminology," Lewis said. "People reported that it caused problems both in consumer education and with professional communication."

DRVs

DRVs for the energy-producing nutrients (fat, carbohydrate, protein, and fiber) are based on the number of calories consumed per day. For labeling purposes, 2,000 calories has been established as the reference for calculating percent Daily Values. This level was chosen, in part, because many health experts say it approximates the maintenance calorie requirements of the group most often targeted for weight reduction: postmenopausal women.

Also, unlike the 2,350-calorie reference that FDA used in its proposal, 2,000 calories is a rounded number, which makes it easier for consumers to calculate their in-

dividual nutrient needs.

The label will include—at least on larger packages—a footnote on the nutrition panel in which daily values for selected nutrients for both a 2,000- and a 2,500-calorie diet are listed. Manufacturers have the option of listing daily values for other calorie levels, if label space allows and as long as the Daily Values for the other two levels are listed, too.

Whatever the calorie level, DRVs for the energy-producing nutrients are always calculated as follows:

- fat based on 30 percent of calories
- saturated fat based on 10 percent of calories
- carbohydrate based on 60 percent of calories
- protein based on 10 percent of calories. (The DRV for protein applies only to adults and children over 4. RDIs for protein for special groups have been established. See table on facing page.)
- fiber based on 11.5 g of fiber per 1,000 calories.

Thus, someone who consumes 3,000 calories a day—a teenage boy, for example—would have a recommended intake for fat of 100 g or less per day. $[0.30 \times 3,000 = 900; 900 \text{ (calories)} \div 9 \text{ (calories per g of fat)} = 100 \text{ g}]$

The DRVs for cholesterol, sodium and potassium, which do not contribute calories, remain the same whatever the calorie level. (See table on facing page.)

Because of the links between certain nutrients and certain diseases, DRVs for some nutrients represent the uppermost limit that is considered desirable. Eating too much fat or cholesterol, for example, has been linked to an increased risk of heart disease. Too much sodium can heighten the risk of high blood pressure in some people.

Therefore, the label will show DVs for fats and sodium as follows:

Counting Calories

How many calories do you need a day?

That question is the key to applying the new nutrition label information to your own individual needs.

As part of new food labeling regulations, FDA and the Food Safety and Inspection Service of the U.S. Department of Agriculture have adopted a 2,000-calorie diet as the basis for calculating Daily Reference Values and the percentages of Daily Values that will appear on the label. However, it's important for people to know their *own* calorie needs because DVs for the energy-producing nutrients—fat, carbohydrate, and protein—are based on recommended percentages of a total day's caloric intake.

For example, no more than 30 percent of a day's calories should come from fat, as recommended by public health experts. So if your daily calorie intake is 2,000, you should limit your calories from fat to 600. (Since there are 9 calories per gram of fat, that translates into no more than about 65 grams of fat.)

But not all people need 2,000 calories a day; some need more, some less. Among the factors that have to be considered, according to Virginia Wilkening, a registered dietitian in FDA's Office of Food Labeling, are:

- body size
- age
- height
- weight
- activity level
- metabolism.



A table, such as the one shown here, that takes into consideration some of these factors can give consumers an idea of what their calorie level should be, she said.

"In order for consumers to use some of the percent Daily Value information effectively, they have to have a concept of what their personal caloric intake is," she said.

But, she added, "It's not something that people have to be exact about. It's a ballpark figure. Their calorie intake might be a little higher one day, a little lower the next. The idea is to have a goal in mind."

The information shown here is from the National Academy of Sciences' 1989 Recommended Dietary Allowances. ■

—P.K.

Recommended Energy Intake

Category	Age	Calories Per Day		
		Light Activity	Moderate Activity	Heavy Activity
Children	4-6		1,800	
	7-10		2,000	
Males	11-14		2,500	
	15-18		3,000	
	19-24	2,700	3,000	3,600
	25-50	3,000	3,200	4,000
	51+		2,300*	
Females	11-18		2,200	
	19-24	2,000	2,100	2,600
	25-50	2,200	2,300	2,800
	51+		1,900*	

Pregnant women in their second and third trimesters should add 300 calories to the figure the table indicates for their age. Nursing mothers should add 500.

* based on light to moderate activity

Activity Levels

Very Light: Driving, typing, painting, laboratory work, ironing, sewing, cooking, playing cards, playing a musical instrument, other seated or standing activities

Light: Housecleaning, child care, garage work, electrical trade

work, carpentry, restaurant work, golf, sailing, table tennis, walking on a level surface at 2.5 to 3 miles per hour

Moderate: Weeding, hoeing, carrying a load, cycling, skiing, tennis, dancing, walking 3.5 to 4 miles per hour

Heavy: Heavy manual digging, tree felling, basketball, climbing, football, soccer, carrying a load uphill

Alphabet Soup Made Appetizing



DVs (Daily Values): a new dietary reference term that will appear on the food label. It is made up of two sets of references, DRVs and RDIs.

DRVs (Daily Reference Values): a set of dietary references that applies to fat, saturated fat, cholesterol, carbohydrate, protein, fiber, sodium, and potassium.

RDIs (Reference Daily Intakes): a set of dietary references based on the Recommended Dietary Allowances for essential vitamins and minerals and, in selected groups, protein. The name "RDI" replaces the term "U.S. RDA."

RDAs (Recommended Dietary Allowances): a set of estimated nutrient allowances established by the National Academy of Sciences. It is updated periodically to reflect current scientific knowledge.

Although consumers will continue to see vitamins and minerals expressed as percentages on the label, these percentages now refer to the Daily Values.

- total fat: less than 65 g
- saturated fat: less than 20 g
- cholesterol: less than 300 mg (milligrams)
- sodium: less than 2,400 mg

RDIs Replace U.S. RDAs

Unlike DRVs, which are a new concept, many consumers may already have a good idea of what the RDIs are. That's because the RDIs (the former U.S. RDAs used by FDA) have been around for almost 20 years as the established estimated values for vitamins, minerals and protein.

The provisions of the Nutrition Labeling and Education Act and the Dietary Supplement Act of 1992 require FDA to retain these estimated values for at least another year.

Although consumers will continue to see vitamins and minerals expressed as percentages on the label, these percentages now refer to the Daily Values.

Getting to Know DVs

Like any new concept, DVs may take some getting used to but, through education and practice, FDA and USDA believe it soon will become second nature to many consumers.

"As more and more new labels make their way into the marketplace," Lewis said, "people will gradually become familiar with the DV term and be able to use the information effectively."

"I think consumers are going to find it very helpful," she said. ■

Paula Kurtzweil is a member of FDA's public affairs staff.

Ingredient Labeling

WHAT'S IN A FOOD?

by Marian Segal

*"Yankee Doodle went to town a ridin' on a pony,
Stuck a feather in his hat and called it
Macaroni."*

MR. DOODLE can call his hat whatever he likes. Pasta makers, however, have long had to be very specific about what they call "macaroni." That's because since shortly after the Federal Food, Drug, and Cosmetic Act was passed in 1938, macaroni, along with some other foods people commonly prepared at home in those days, was exempted from the law's requirement that food manufacturers list their products' ingredients on the food label. Instead, the new act provided for "standards of identity"—prescribed recipes—for these foods, which the manufacturers had to follow.

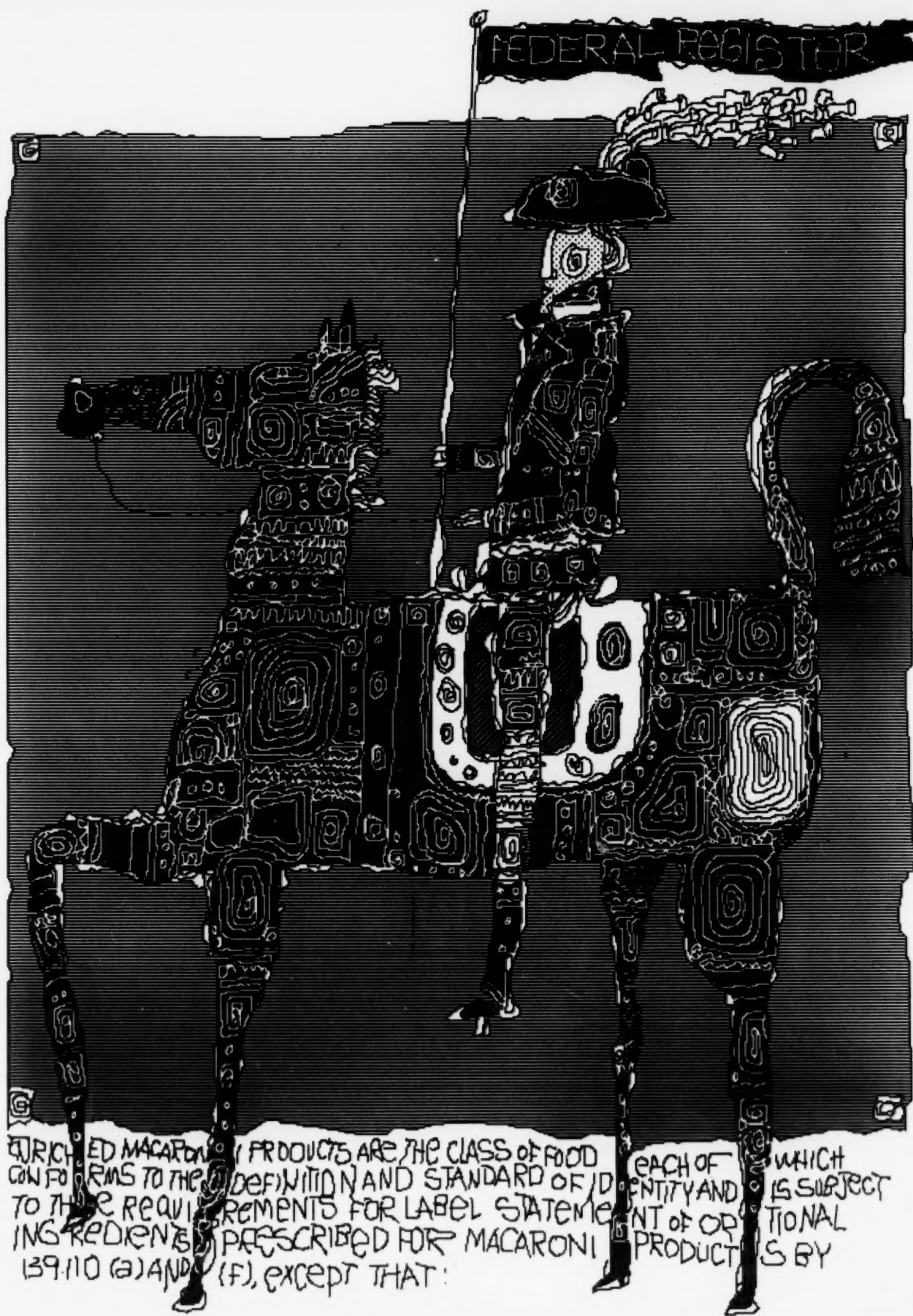
"The law resulted in standardized recipes for such foods as dairy products, mayonnaise, ketchup, jelly, and orange juice," says Elizabeth Campbell, director of the programs and enforcement policy division in the Office of Food Labeling of FDA's Center for Food Safety and Applied Nutrition. "When a consumer bought a jar of jelly she knew it would have at least 45

percent fruit, as the standard provided, because that's what it takes to make jelly," she explained. "It's roughly half fruit and half sugar. People knew that because they used to make it themselves."

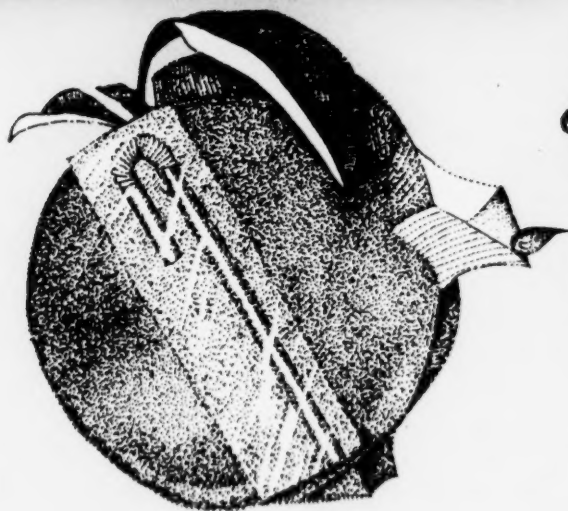
Well, maybe so, but we're in the '90s now, and with the fast pace of today's lifestyles, homemade breads and jellies mostly exist in Grandma's memories. It can hardly be taken for granted that people still know what's in those standardized foods. And yet, more and more, health-conscious consumers and people with dietary restrictions want and need to know what's in the foods they buy.

So, the law is changing to catch up with the times. FDA now requires that ingredients for all standardized foods be listed on the label, the same as for all other foods. This is one of several provisions of a final rule published in the Jan. 6, 1993, *Federal Register* concerning declaration of ingredients on food labels. (The U.S. Department of Agriculture requires full ingredient labeling on all meat and poultry products, including standardized products, such as chili or sausages.)

Two of the provisions of the rule on declaration of ingredients respond directly



When Is Peach Juice Apple Juice?



When it comes to juice labeling, there are those who would disagree with Shakespeare's sentiment that "a rose by any other name would smell as sweet." If the label implies that it's peach juice, they contend, it shouldn't consist mostly of apple and white grape juice—especially without saying so on the label.

The final rule on percentage juice declaration published in the Jan. 6, 1993, *Federal Register* will help remedy this problem. Beginning May 8, 1993, juice manufacturers will have to declare the total amount of juice in a beverage. (As this article goes to press, FDA is proposing to exempt from this requirement until May 8, 1994, foods that claim to be beverages containing vegetable or fruit juice.)

In addition, when the label of a multi-juice beverage names one or more, but not all, the juices in the beverage, and if the named juices are present in minor amounts, manufacturers must either:

- state the beverage is flavored by the named juice, such as "raspberry flavored juice drink," or
- declare the amount of the named juice in a 5 percent range, as "juice blend, 2 to 7 percent raspberry juice."

The rule-making process on declaration of percentages of juice goes back many years, beginning with debates over standards of identity for diluted juice beverages.

In 1974, FDA proposed a regulation to establish common or usual names for juice drinks instead of developing standards.

After many objections, tie-ups, and reworkings—including a final regulation in 1980 that never had an effective date and two more proposals in 1984 and 1987—the Nutrition Labeling and Education Act came along in 1990 requiring that "a food that purports to be a beverage containing juice must declare the percent of total juice on the information panel."

But this alone would not solve the problem of misleading labels. Many manufacturers today use bland juices, like apple or white grape, as diluents instead of water and call the product a 100 percent juice blend.

"Some of these labels are just not informative," Campbell says. "The label says 100 percent juice blend or 100 percent natural juices, but only the expensive juices—the raspberry or strawberry, which are in smaller amounts—appear prominently on the principal display panel. You have to look for the grape and the apple in the fine print."

To correct this, FDA elaborated on the 1990 law, proposing that manufacturers be required to declare not only the total percent of juice, but the percent of each juice named or pictured on the label of a multi-juice beverage.

In responding to the proposal, however, manufacturers protested that this require-

ment would be impractical and difficult to comply with. They explained that juice, as an agricultural product, varies in strength, flavor, solids, and color. If they were required to state a percentage, they wouldn't have the flexibility necessary to adjust the amount of juice—using a little bit less or a little bit more or a little sweetening—to get the desired flavor. Nor would they be able to vary their formulas as driven by fluctuations in cost or availability of individual juices.

In addition, they said the amount of juice they use in their formulations is proprietary information, and requiring them to reveal this information in 1 percent increments would force them to divulge their secret formulas.

The final rule allowing a statement that the beverage is flavored, or declaring the amount of juice named in a 5 percent range, addresses manufacturers' concerns, while providing more accurate information for consumers. ■

—M.S.

FDA

*now requires that ingredients for all standardized foods be
listed on the label, the same as for all other foods.*



INGREDIENTS: MUTTON BROTH, CARROTS, BARLEY, COOKED
MUTTON, POTATOES, WATER, SALT, CORN STARCH, COOKED
BEEF, MUTTON FAT, VEGETABLE OIL, YEAST EXTRACT, AND
HYDROLYZED VEGETABLE PROTEIN, MONOSODIUM
GLUTAMATE, SPICE EXTRACTS, DEHYDRATED PARSLEY, BETA
CAROTENE FOR COLOR AND CARAMEL COLOR.

DISTRIBUTED BY:
CAMPBELL SOUP COMPANY
CAMDEN, N.J., U.S.A. 08103-1701
PRODUCT OF CANADA

New food labels will have to provide more information about some ingredients. For example, the terms "hydrolyzed vegetable protein," "hydrolyzed animal protein," or simply "hydrolyzed protein"—permitted in the past—will now have to identify the protein source, such as corn, casein or other.

to the 1990 Nutrition Labeling and Education Act (NLEA). One is the requirement to list ingredients in standardized foods; the other requires the label to list FDA-certified color additives by name.

Before passage of the NLEA, the Food, Drug, and Cosmetic Act did not require flavorings, colorings or spices to be identified by their common or usual names. Instead, they could be declared collectively under the general terms "flavorings,"

"spices" or "colorings." Under the NLEA, however, color additives that FDA certifies for food use—FD&C colors Yellow No. 5, Red No. 40, Red No. 3, Yellow No. 6, Blue No. 1, Blue No. 2, and Green No. 3, and their lakes (specially formulated nonsoluble colors)—now must be declared on all foods except butter, cheese, and ice cream. Colors exempt from certification, such as caramel, paprika, and beet juice, do not have to be specifically identi-

fied; they can still be listed simply as "artificial colors."

People often look to the ingredient label for health reasons—perhaps to avoid substances they are allergic or sensitive to—or for religious or cultural reasons.

Manufacturers must comply with the requirements for ingredient listing of standardized foods and declaration of certified color additives by May 8, 1993. Other provisions of the final rule become effective May 8, 1994.

Caseinate

If it says "nondairy," does it mean no milk? Many people are not aware that certain products claiming to be nondairy, such as some coffee whiteners, contain a milk derivative called caseinate, in this case used to whiten effectively.

"People expect there to be no milk ingredients in products marketed as dairy substitutes," Campbell says, "but some states require the label 'nondairy.' This issue is particularly important for people with milk allergies. The nondairy label may lead consumers to think that caseinates are not milk derived. Furthermore, it guides people away from even checking the label for milk-derived ingredients."

Under the new rule, caseinate will have to be identified as a milk derivative in the ingredient statement when it's used in foods that claim to be nondairy. This requirement will help to flag it for casein-sensitive people.

Protein Hydrolysates

Consumers will get more information about protein hydrolysates in their food, too. Hydrolyzed proteins (proteins broken down by acid or enzymes into amino acids) are added to foods to serve various functions. They can be used as leavening agents, stabilizers (to impart body or im-

Standardized Foods

To comply with the new food labeling laws, manufacturers now will have to list ingredients that are in standardized foods.

The following product categories of standardized foods are:

- milk and cream
- cheeses and related products
- frozen desserts
- bakery products
- cereal flours and related products
- macaroni and noodle products
- canned fruits
- canned fruit juices
- fruit butters, jellies, and jams or preserves
- fruit pies
- canned vegetables
- vegetable juices
- frozen vegetables
- eggs and egg products
- fish and shellfish
- cacao products (for example, cocoa, chocolate)
- tree nut and peanut products
- margarine
- sweeteners and table syrups
- food dressings and flavorings
(for example, mayonnaise, salad dressing, vanilla flavoring)

People often look to the ingredient label

for health reasons, or

for religious or cultural reasons.

prove consistency, for example), thickeners, flavorings, flavor enhancers, and as a nutrient (protein source), to name a few uses.

Since the law does not require flavors to be identified by their common or usual names, some in industry have made a practice of declaring protein hydrolysates as "flavorings" or "natural flavors" even when they are used as flavor enhancers—a use not exempt from declaration. After reviewing the data, FDA concluded that protein hydrolysates added to foods as flavorings always function as flavor enhancers as well and, as such, must be declared by their common or usual name.

The source of protein in hydrolysates used for flavor-related purposes also must be identified. Previously the general terms "hydrolyzed vegetable protein," "hydrolyzed animal protein," or simply "hydrolyzed protein" were permitted, but the new regulation requires identification of the specific protein source, such as "hydrolyzed corn protein" or "hydrolyzed casein." There are two reasons for this.

First, the law requires that the common or usual name of a food should adequately describe its basic nature or characterizing properties or ingredients. FDA reasoned that the more general terms "animal" and "vegetable" don't meet this requirement because protein hydrolysates from different sources best serve different functions. Manufacturers select protein hydrolysates from specific sources depending on how they will be used in a product. Hydrolyzed casein is generally used in canned tuna, for example, whereas hydrolyzed wheat protein is used in meat flavors.

Second, the source of the additive is particularly important to consumers who have special dietary requirements,

whether for religious, cultural or health reasons. If hydrolyzed casein is added to canned tuna, for example, it must be identified as such, rather than simply as "hydrolyzed protein" or "hydrolyzed milk protein."

Furthermore, after reviewing comments on the June 1991 proposal, the agency concluded that to minimize confusion, the source of protein in hydrolysates used for non-flavor-related purposes should also be identified. Thus, the source of all protein hydrolysates—regardless of use—will now have to be identified.

Other final provisions of the new rule will:

- Permit voluntary inclusion of the food source in the names of sweeteners. For example, "corn sugar monohydrate" would be permitted in addition to names previously permitted, such as "dextrose" or "dextrose monohydrate."
- Provide a uniform format for voluntary declaration of percentage ingredient information. Manufacturers who choose to declare ingredients by percent of content would present them by weight rather than volume to avoid inconsistent calculations. Firms may use percentage declarations for as many or as few ingredients as they choose, as long as the information is not misleading. Manufacturers must still list ingredients in descending order, by weight, as required by law.
- Require label declaration of sulfiting agents in standardized foods. This is required because some people are sensitive to these preservatives. FDA has required listing of sulfiting agents in nonstandardized foods since 1986. ■

Marian Segal is a member of FDA's public affairs staff.

Nutrition Info Available For Raw Fruits, Vegetables, Fish

by Paula Kurtzweil

Customers of D'Agostino Supermarkets in New York have taken to reading the writing on the wall—and at the counter, in the aisles, and just about everywhere else that store managers have posted nutrition information on raw produce and fish.

They're reading about the amounts of sodium, vitamins A and C, calcium and iron, and other nutrients in their favorite fruits and vegetables and fish. And, thanks to accompanying take-away brochures, they're learning how those foods can help them follow the Dietary Guidelines for Americans.

"Customers are interested," acknowledges Mary Moore, director of public affairs for the company. "They're picking up the brochures; they're taking them home. And our managers tell us they see people reading the charts all the time."

They're not alone. Food shoppers across the country are helping themselves to the same type of information. It's all part of FDA's voluntary point-of-purchase nutrition information program for raw fruits, vegetables and fish, and D'Agostino Supermarket Inc. is one of many grocers participating.

It's well that these grocers are participating because under FDA guidelines, at least 60 percent of a nationwide sample of grocery stores surveyed in late 1992 must have been in compliance at that time. If they're not, FDA is required by law to make the program mandatory.

Grocers have some flexibility: They can choose from a variety of ways in which to convey nutrition information—poster, brochure, leaflet, notebook, or stickers—as long as those materials are available in the appropriate food department.

They're required to provide nutrition information only for the 20 most frequently eaten raw fruits, vegetables and fish. (See accompanying lists). And, they have to provide information only on calories and eight nutrients.

However, guidelines for voluntary labeling of raw produce and fish will be revised this year to make them more consistent with mandatory nutrition labeling requirements.

Setting Standards

FDA established the current guidelines for voluntary nutrition information in November 1991, in accordance with the Nutrition Labeling and Education Act of 1990. Although the law mandates nutrition labeling for almost all processed foods, it allows voluntary point-of-purchase nutrition information for raw fruits, vegetables and fish—as long as a sufficient number of retailers participate.

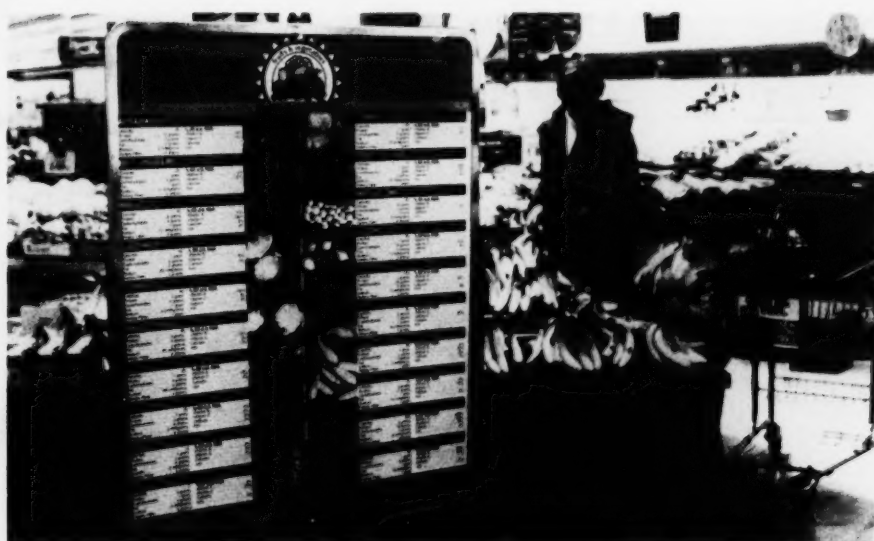
According to Jean Pennington, Ph.D., a registered dietitian and associate director of dietary surveillance in FDA's Center for Food Safety and Applied Nutrition, the program is intended to give retailers flexibility while ensuring that as many consumers as possible have access to consistent, reliable information.

Offering in-store nutrition information on these types of foods isn't new, she noted. Many grocers have been doing it on their own for years.

For example, almost 10 years ago, Schnuck Markets Inc., a 60-store grocery chain headquartered in St. Louis, began offering customers its *Nutri Guide* book-



Lucille O'Connell, of metropolitan St. Louis, checks the nutritional content of her favorite fish at her local supermarket. Many grocers are offering such information under FDA's new voluntary point-of-purchase nutrition information program for raw foods. This photo and the one on the facing page were taken in Schnuck's Kirkwood, Mo., store.



A large poster with nutrition information about the 20 most popular raw vegetables is prominently placed in the produce section. It is one of several options grocers may use to present nutrition information for raw produce and fish.

let—which lists calorie, fat, cholesterol, sodium, and fiber content of nearly 2,500 in-store foods, including perishable items.

And Giant Foods Inc., a Washington, D.C., area retail chain headquartered in Landover, Md., has been selling its *Eat for Health Food Guide* since the 1980s. This guide, too, provides nutrition information on thousands of store products, including fresh fruits and vegetables and raw fish.

What is new is that, for the first time, consumers at grocery stores across the country will have access to the same basic nutrition information. "We're aiming for consistency here," Pennington said. "From store to store and from state to state."

What Shoppers Will See

That's why the program, although voluntary, carries some mandatory components. Chief among them is the information that must be provided.

To meet the FDA guidelines, point-of-purchase nutrition information for raw fruits, vegetables and fish must include the following:

- name of the fruit, vegetable or fish that

has been identified by FDA as being one of the 20 most commonly eaten in the United States

- serving size
- calories per serving
- amount of protein, total carbohydrates, total fat, and sodium per serving
- percent of the U.S. Recommended Daily Allowances for iron, calcium, and vitamins A and C per serving.

This information is required because FDA believes it's important for consumers to know which foods will increase one's intake of nutrients and which will not.

Declaring the percent of U.S. RDAs for thiamin, riboflavin, niacin, and protein, and the amounts of complex carbohydrates, sugars, dietary fiber, saturated fat, and cholesterol is optional.

The serving size, determined by FDA, is defined as that portion of food "customarily consumed per eating occasion."

For raw produce, the serving size is of ten an individual unit (for example, one medium orange or two stalks of celery), or a fraction of a unit (for example, one-sixth of a medium head of lettuce)—whichever

is most appropriate for the product.

For fish, the serving size is a 3-ounce, or 85-gram, *cooked* weight—without added fat or seasoning.

According to Pennington, using a cooked weight is a departure from usual FDA practice, which is to require food labels to state a serving size based on a measurement of the food as purchased. In the case of raw fish, however, FDA officials feared that the word "raw" on the label might lead some consumers to conclude that eating raw fish is OK, when in fact it generally is not.

"We certainly don't want to suggest that eating raw fish is a safe thing to do," she said.

While some types of shellfish have been customarily eaten raw, and sushi and sushimi are considered by some to be raw fish delicacies, there are dangers of food-borne illness from eating raw fish. In particular, people with liver diseases, certain gastrointestinal disorders, diabetes mellitus, or weakened immune systems are advised not to eat raw molluscan shellfish, such as oysters, clams, mussels, and scallops. And sushi and sushimi must be commercially frozen to kill any parasites.

Presenting Nutrition Information

Equally important as the type of information is the manner in which it is conveyed. Unlike processed, prepackaged food, raw produce and fish do not lend themselves well to individual labeling.

So FDA is allowing retailers to display nutrition information on large placards or to list it in consumer pamphlets or brochures—provided the information is in the appropriate food department for easy consumer access. If they want, retailers may place nutrition information on individual food wrappers or, when appropriate, on stickers affixed to the outside of a food (for example, bananas).

One trade organization, the Food Marketing Institute, is making the job easier for retailers. It offers brochures, charts and posters that contain all the necessary information. The materials were developed as part of the Nutri-Facts Program, a point-of-purchase nutrition information project begun in 1985 and now sponsored by FMI

A Serving of Nutrition Info at the Meat Counter

Nutrition information for raw meat and poultry may be coming soon to a grocery store near you.

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture has established a voluntary nutrition information program for 45 of the best-selling cuts of raw meat and poultry. Similar to FDA's voluntary point-of-purchase nutrition information program for raw fish and produce, FSIS' program calls for "significant" compliance by grocers. If significant participation is not found, FSIS will consider making the program mandatory.

FSIS' guidelines, which were issued in January 1993, go into effect July 6, 1994, although some grocery stores may start offering the information sooner. FSIS will check for compliance every two years, beginning in May 1995.

Like FDA's program, FSIS' voluntary program targets a select group of foods—major cuts of raw single-ingredient meat and poultry products. And, like FDA's, FSIS' program allows nutrition information to be presented on posters, brochures and other point-of-purchase materials—as long as they are near the food. Information also can be provided on the package label.

To meet FSIS guidelines, point-of-purchase nutrition information for raw meats and poultry must include the following:

- name of the meat or poultry cut
- serving size based on raw or cooked weight
- calories per serving
- calories from total fat per serving
- amount per serving—by weight and by percentage of Daily Value—for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber



- amount by weight of sugars and protein
- percentage of Daily Values per serving for vitamins A and C, and calcium and iron

Optional information includes:

- servings per package or container
- calories from saturated fat per serving
- amount per serving for stearic acid, polyunsaturated fat, monounsaturated fat, potassium, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate (the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, if declared)
- percentage of Daily Values per serving for other essential vitamins and minerals
- lists of daily values for selected nutrients for 2,000- and 2,500-calorie daily diets.

Point-of-purchase materials are not subject to the nutrition labeling format requirements for packaged items.

Major meat and poultry cuts are:

Beef

chuck blade roast
loin top loin steak
rib roast large end
round eye round steak
round top round steak
round tip roast
chuck arm pot roast
loin sirloin steak
round bottom round steak
brisket
rib steak small end

loin tenderloin steak
regular ground
extra lean ground

Pork

loin chop
loin country style ribs
loin top loin chop boneless
loin rib chop
spareribs
loin tenderloin
loin sirloin roast
shoulder blade steak
loin top roast boneless ground

Lamb

shank
shoulder arm chop
shoulder blade chop
rib roast
loin chop
leg

Veal

shoulder arm steak
shoulder blade steak
rib roast
loin chop
cutlets

Chicken and Turkey

whole*
breast
wing
drumstick
thigh

* without neck and giblets. Separate nutrient panels for white and dark turkey are optional.

—P.K.

Most Common Fruits, Vegetables and Fish Sold Raw

Top 20 Fruits

- banana
- apple
- watermelon
- orange
- cantaloupe
- grape
- grapefruit
- strawberry
- peach
- pear
- nectarine
- honeydew melon
- plum
- avocado
- lemon
- pineapple
- tangerine
- sweet cherry
- kiwi fruit
- lime



Top 20 Vegetables

- potato
- iceberg lettuce
- tomato
- onion
- carrot
- celery
- sweet corn
- broccoli
- green cabbage
- cucumber
- bell pepper
- cauliflower
- leaf lettuce
- sweet potato
- mushroom
- green onion
- green (snap) bean
- radish
- summer squash
- asparagus



Top 20 Fish

- shrimp
- cod
- pollock
- catfish
- scallop
- Atlantic/coho salmon
- flounder
- sole
- oyster
- orange roughy
- Atlantic/Pacific and jack mackerel
- ocean perch
- rockfish
- whiting
- clam
- haddock
- blue crab
- rainbow trout
- halibut
- lobster



and nine other industry trade groups. (See inside back covers of the May 1992 through November 1992 *FDA Consumer*.)

Live demonstrations, and videotapes and other electronic means also may be used to convey nutrition information, but only as adjuncts to the print pieces. In FDA's view, non-print media are less likely than print media to be dependably available. Breakdown of videotape players, for example, may make the information unavailable for any length of time.

Other means of conveying nutrition information for these foods may exist, and, according to Pennington, FDA would like to see retailers and others identify them.

"We encourage retailers to experiment in finding ways that best convey nutrition information to consumers," she said. "And we hope that they share their findings with us."

Checking for Compliance

FDA plans to keep tabs on how well food retailers comply with the voluntary

guidelines. Under the Nutrition Labeling and Education Act, the program can remain voluntary only as long as there is "substantial compliance."

FDA defines "substantial" as at least 60 percent of a nationwide representative sample of grocery stores. Grocers are considered in compliance if at least 90 percent of the 20 most commonly eaten raw fish and at least 90 percent of the 40 most commonly eaten types of raw produce sold in their stores are properly labeled. Thus, retailers have to provide nutrition information for only those most commonly eaten fruits, vegetables and fish that they sell in their stores.

FDA will check compliance by surveying every two years a sample of 2,000 U.S. food stores that sell produce or raw fish. Results of the first survey, which began in late 1992, will be issued in an FDA report due to Congress in May 1993.

If substantial compliance is found, the program will continue on a voluntary basis. But if FDA determines that compli-

ance is not substantial, it will issue new regulations *mandating* point-of-purchase nutrition information for raw fruits, vegetables and fish.

In addition, at least every two years, FDA will revise and publish in the *Federal Register* nutrition labeling data for the 20 most frequently eaten raw fruits, vegetables and fish.

At the same time, it will conduct a survey of food retailers and issue a report to Congress on the status of the voluntary program.

At least one food retailer hopes to be part of those proceedings—D'Agostino Supermarkets, where, according to spokeswoman Moore, voluntary in-store nutrition information programs are in place in all 25 of its chain stores.

"I certainly hope [FDA comes] to D'Agostino," she said. "Because we're more than ready." ■

Paula Kurtzweil is a member of FDA's public affairs staff.



THE FOOD PYRAMID- FOOD LABEL CONNECTION

by Etta Saltos, Ph.D., R.D.

What foods fit in a healthy diet? How can you compare the nutritional values of food? Can the new food label help you answer these questions?

It can, if you use the label information to follow the Dietary Guidelines for Americans. (See accompanying article.)

Food Pyramid

The Food Guide Pyramid can help you put the Dietary Guidelines into action. The pyramid illustrates the research-based food guidance developed by the U.S. Department of Agriculture and supported by the Department of Health and Human Services. It is based on USDA's research on what foods Americans eat, what nutrients are in these foods, and how to make the best food choices to promote good health. It outlines what to eat each day, but it is not a rigid prescription. You can use it as a general guide in choosing a healthful diet that is right for you. The pyramid calls for eating a variety of foods to get the nutrients you need, and, at the same time, the right amount of calories to maintain a healthy weight. It also focuses on fat because most American diets are too high in fat, especially saturated fat.

You don't have to avoid foods that are high in fat, saturated fat, cholesterol, and sodium completely. It's your average in-

take over a few days, not in a single food or even a single meal, that's important. If you eat a high-fat food or meal, balance your intake by choosing low-fat foods the rest of the day or the next day. The new food label can help you "budget" your intake of fat, saturated fat, cholesterol, and sodium over several days.

The new food label also can help you identify good sources of fiber and vitamins and minerals.

Look to the Label

How does it do this? First, descriptors such as "free," "low" or "reduced" on the front of the package can signal that a food is low in a certain dietary component, such as calories, fat, saturated fat, or sodium. Eating those foods can then help you moderate your intake of these and other nutrients.

Descriptors such as "good source" and "high" can help you identify foods that contain significant amounts of dietary fiber, vitamins, and minerals. (See "A Little 'Lite' Reading" on page 29.)

Claims about the relationship between a nutrient or a food and the risk of a disease or health-related condition also may show up on the front of the package of FDA-regulated products. These are called health
(Continued on page 60)



"Here's your problem . . . You've been reading the Food Pyramid upside down!"

Food Guide Pyramid

A Guide to Daily Food Choices

Fats, Oils, & Sweets
USE SPARINGLY

KEY

- Fat (naturally occurring and added) ■ Sugars (added)

These symbols show fats, oils, and added sugars in foods.

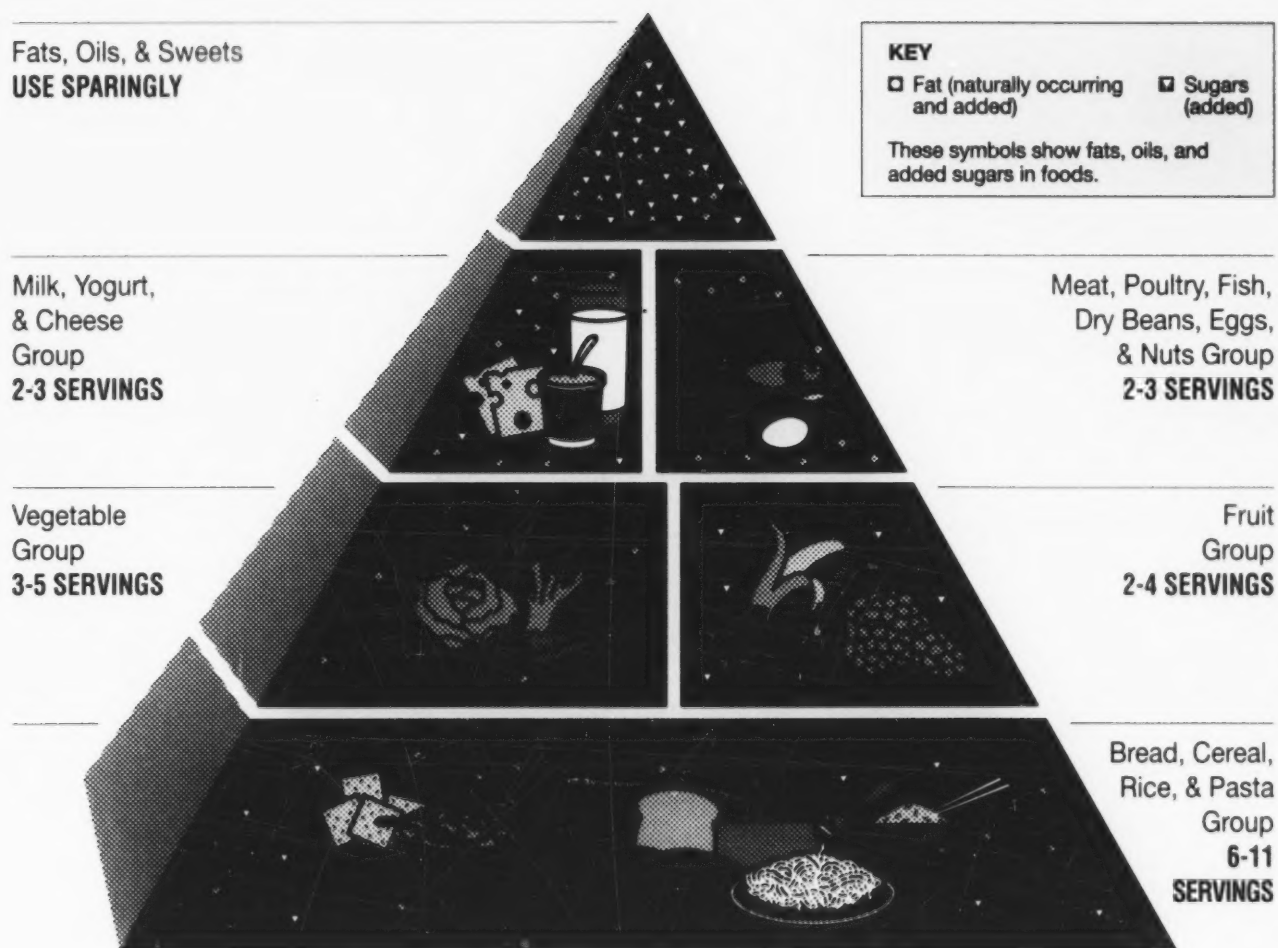
Milk, Yogurt, & Cheese Group
2-3 SERVINGS

Meat, Poultry, Fish, Dry Beans, Eggs, & Nuts Group
2-3 SERVINGS

Vegetable Group
3-5 SERVINGS

Fruit Group
2-4 SERVINGS

Bread, Cereal, Rice, & Pasta Group
6-11 SERVINGS



How to Use The Daily Food Guide

What counts as one serving?

Breads, Cereals, Rice, and Pasta

1 slice of bread
1/2 cup of cooked rice or pasta
1/2 cup of cooked cereal
1 ounce of ready-to-eat cereal

Vegetables

1/2 cup of chopped raw or cooked vegetables
1 cup of leafy raw vegetables

Fruits

1 piece of fruit or melon wedge
3/4 cup of juice
1/2 cup of canned fruit
1/4 cup of dried fruit

Milk, Yogurt, and Cheese

1 cup of milk or yogurt
1-1/2 to 2 ounces of cheese

Meat, Poultry, Fish, Dry Beans, Eggs, and Nuts

2-1/2 to 3 ounces of cooked lean meat, poultry, or fish
Count 1/2 cup of cooked beans, or 1 egg, or 2 tablespoons of peanut butter as 1 ounce of lean meat (about 1/3 serving)

Fats, Oils, and Sweets

LIMIT CALORIES FROM THESE especially if you need to lose weight

The amount you eat may be more than one serving. For example, a dinner portion of spaghetti would count as two or three servings of pasta.

How many servings do you need each day?

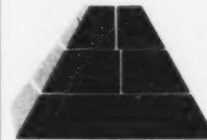
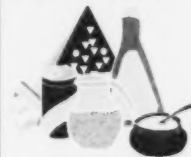
Calorie level*	about 1,600	about 2,200	about 2,800
Bread group	6	9	11
Vegetable group	3	4	5
Fruit group	2	3	4
Milk group	**2-3	**2-3	**2-3
Meat group	2, for a total of 5 ounces	2, for a total of 6 ounces	3, for a total of 7 ounces

* These are the calorie levels if you choose lowfat, lean foods from the 5 major food groups and use foods from the fats, oils, and sweets group sparingly.

** Women who are pregnant or breastfeeding, teenagers, and young adults to age 24 need 3 servings.

A Closer Look at Fat and Added Sugars

The small tip of the Pyramid shows fats, oils, and sweets. These are foods such as salad dressings, cream, butter, margarine, sugars, soft drinks, candies, and sweet desserts. Alcoholic beverages are also part of this group. These foods provide calories but few vitamins and minerals. Most people should go easy on foods from this group.



Some fat or sugar symbols are shown in the other food groups. That's to remind you that some foods in these groups can also be high in fat and added sugars, such as cheese or ice cream from the milk group, or french fries from the vegetable group. When choosing foods for a healthful diet, consider the fat and added sugars in your choices from all the food groups, not just fats, oils, and sweets from the Pyramid tip.

Find Your Fat Limit

Recommended upper limits of total fat and saturated fat intake at different calorie levels:

	Calories			
	1,600	2,000	2,500	2,800
Total Fat (grams)	53	65	80	93
Saturated Fat (grams)	18	20	25	31

A daily diet of 2,000 calories—the basis for the “% Daily Value” on food labels—is about right for women who engage in moderate activity, such as an occasional tennis game. It is also the target calorie level for teenage girls and sedentary men.



Descriptors such as “free,” “low” or “reduced” on the front of the package can signal that a food is low in a certain dietary component, such as calories, fat, saturated fat, or sodium.

(Continued from page 56)

claims, and FDA has authorized seven of them. They can help you identify foods with certain nutritional qualities that are of interest to you. (See “Look for ‘Legit’ Health Claims on Foods” on page 20.)

However, you don’t have to select only foods with descriptors or health claims on the label to follow the Dietary Guidelines. In moderation, all foods can fit into a healthy diet.

Second, look at the nutrition panel, now titled “Nutrition Facts.” With a few exceptions, the nutrition panel will list calories, calories from fat, and the amount of nutrients of greatest public health concern contained per serving of the food. (See “‘Nutrition Facts’ to Help Consumers Eat Smart” on page 34.) Similar information also will be available voluntarily for some raw foods. (See “Nutrition Info Available for Raw Fruits, Vegetables, Fish” on page 51.)

On the nutrition panel, nutrient content will be expressed not only as an amount by weight but also as a percent of the Daily Value, or DV—a new label reference value. (See “‘Daily Values’ Encour-

Descriptors such as “good source” and “high” can help you identify foods that contain significant amounts of dietary fiber, vitamins, and minerals.



Teenage boys are among those who may need 2,500 calories a day. Daily values for that calorie level are required on the labels of larger food packages.

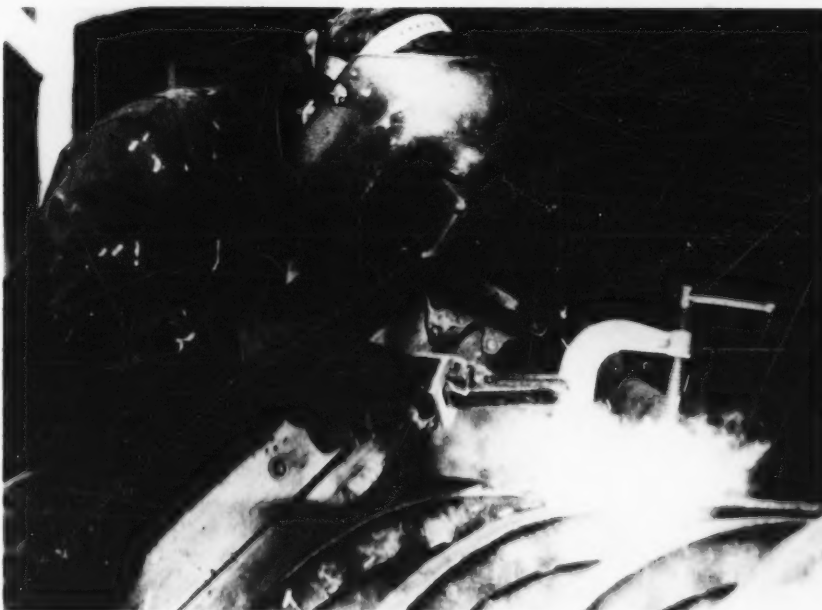
age Healthy Diet” on page 40.)

These percentages can help you decide whether a food contributes a lot or a little of a particular nutrient. Lower percentages indicate the food contributes less of the nutrient, and higher percentages indicate that it contributes more of the nutrient.

Look to see whether the nutrients you would like to get more of (such as carbohydrate, dietary fiber, and vitamins and minerals) have high percentages and the nutrients you may need to limit (such as fat, cholesterol and sodium) have low percentages. The percent Daily Values, while based on a 2,000-calorie diet, will indicate in a relative way the nutritional contributions of a food to your diet regardless of your calorie intake.

Also, because serving sizes are now more uniform across product lines, comparing the nutritional content of foods is easier.

However, the amount of food you eat may be different from the stated serving size. For example, the serving size for ice cream is a half cup, so if you usually eat one cup of ice cream, you would have to double the number of calories and the per-



Men and women engaged in heavy manual labor or heavy activity, such as daily running or team sports, may need at least 2,800 calories a day to maintain an appropriate weight. Although this figure is not on the food labels, people in this category can use the percent Daily Values to guide them.



Children are among those people needing fewer calories than the target levels for adults. Persons older than 3 also can use the percent Daily Values to help them select appropriate nutrient intakes.

The serving size for ice cream is a half cup, so if you usually eat one cup of ice cream, you would have to double the number of calories and the percentages of the Daily Values listed to learn the nutrient content of the portion you eat.

percentages of the Daily Values listed to learn the nutrient content of the portion you eat.

Figuring Fat

While the food label provides a reliable general guide for most people, you may want to use the information on it to make more personal choices.

You may be concerned about fat, for example. The Dietary Guidelines suggest you eat a diet providing 30 percent or less of calories from fat and less than 10 percent of calories from saturated fat. Thus, the recommended upper limit on grams of fat and saturated fat in your diet depends on the calories you need (see chart on page 60). Percent DVs for fat and saturated fat are based on a 2,000-calorie diet, which is about right for moderately active women, teenage girls, and sedentary men.

Some people keep a running total of the amount of fat and saturated fat they eat in a day and compare this to their target level. If you eat about 2,000 calories a day, you can simply monitor the percent DV information from the foods you eat so that the total is close to or less than 100 percent over the day.

If you eat fewer than or more than 2,000 calories a day, you can keep a total of the actual amount of fat and saturated fat contained in the foods you eat. This information is listed immediately after the nutrient name (for example, "Total Fat 13 g").

Daily values based on an intake of 2,500 calories a day are listed in a footnote, at least on the nutrition panels of larger packages. These values can be used as a target level for many men, teenage boys, and active women.

The chart on page 60 lists recommended upper limits of fat and saturated fat intakes for other calorie levels. Many older adults, children, and sedentary women need fewer than 2,000 calories a day and may want to select target levels based on 1,600 calories a day. Some active men and teenage boys and very active women may want to select target levels based on 2,800 calories per day.

Sugars and Others

The percent DV column also can be used to help you moderate your intake of sodium and cholesterol. The Daily Values for sodium and cholesterol are the same

Dietary Guidelines

The Dietary Guidelines, developed by the Department of Health and Human Services and the U.S. Department of Agriculture, represent the best, most current advice for healthy Americans 2 years and older. They reflect recommendations of health and nutrition experts, who agree that enough is known about the effect of diet on health to encourage certain eating practices. The seven Dietary Guidelines are:

- **Eat a variety of foods** to get the energy (calories), protein, vitamins, minerals, and fiber you need for good health.
- **Maintain a healthy weight** to reduce your chances of having high blood pressure, heart disease, a stroke, certain cancers, and the most common kind of diabetes.
- **Choose a diet low in fat, saturated fat, and cholesterol** to reduce your risk of heart disease and certain types of cancer. Because fat contains more than twice the calories of an equal amount of carbohydrates or protein, a diet low in fat can help you maintain a healthy weight.
- **Choose a diet with plenty of vegetables, fruits, and grain products** that provide needed vitamins, minerals, fiber, and complex carbohydrates. They are generally lower in fat.
- **Use sugars only in moderation.** A diet with lots of sugars has too many calories and too few nutrients for most people and can contribute to tooth decay.
- **Use salt and other forms of sodium only in moderation** to help reduce your risk of high blood pressure.
- **If you drink alcoholic beverages, do so in moderation.** Alcoholic beverages supply calories, but little or no nutrients. Drinking alcohol is also the cause of many health problems and accidents and can lead to addiction. ■

You don't have to avoid foods that are high in fat, saturated fat, cholesterol, and sodium completely. It's your average intake over a few days, not in a single food or even a single meal, that's important.

for everyone, regardless of total calories consumed, so you do not have to make adjustments based on your caloric needs.

Food labels also can be helpful if you're trying to moderate your sugar intake. The nutrition panel lists the amount of sugars in grams (4 grams is equivalent to 1 teaspoon) in a serving of the food.

Note that this amount includes sugars that are present *naturally* in the food (such as lactose in milk and fructose in fruit), as well as sugars *added* to the food during processing. If you're interested in finding out whether a sweetener has been added to a food, check the ingredient listing. Terms such as "sugar (sucrose)," "fructose," "maltose," "lactose," "honey," "syrup," "corn syrup," "high-fructose corn syrup," "molasses," and "fruit juice concentrate" are used to describe sweeteners added to foods.

If one of these terms appears first or second in the list of ingredients, or if several of them appear, the food is likely to be high in added sugars. A percent DV is not given for sugars because there is no target quantity of sugars to aim for each day.

Labeling of the alcohol content of bev-

erages is regulated by the Bureau of Alcohol, Tobacco, and Firearms. Alcohol content (in percentage by volume) appears on the front panel of some alcoholic beverage labels. Alcohol content of foods and beverages is not required to be listed on the nutrition panel. However, some alcoholic beverages, such as light beers and wine coolers, provide information about the amount of calories, carbohydrate, protein, and fat they contain. You may find this information useful if you're counting calories because alcoholic beverages are generally rich in calories and poor in nutrients.

You'll find lots of information on food labels. So take the time to read them. The information can help you plan a healthful diet that meets the recommendations of the Dietary Guidelines. ■

Etta Saltos is a nutritionist with USDA's Human Nutrition Information Service.

Hungry for More Food Labeling Information?

The FDA/USDA Food Labeling Education Information Center can help. Through its database of educational activities, the center can put you or your organization in touch with trade groups, consumer organizations, health professionals, educators, government agencies, and private companies producing materials on the new food label. You can learn what materials are being developed, who their target audiences are, and how copies can be obtained. You may even find a potential partner for your own particular education project.

To find out more, write or call:

Gina McNeal
Food and Nutrition Information Center/
National Agricultural Library
Room 304, 10301 Baltimore Blvd.
Beltsville, MD 20705-2351
(301) 504-5719
FAX (301) 504-6409

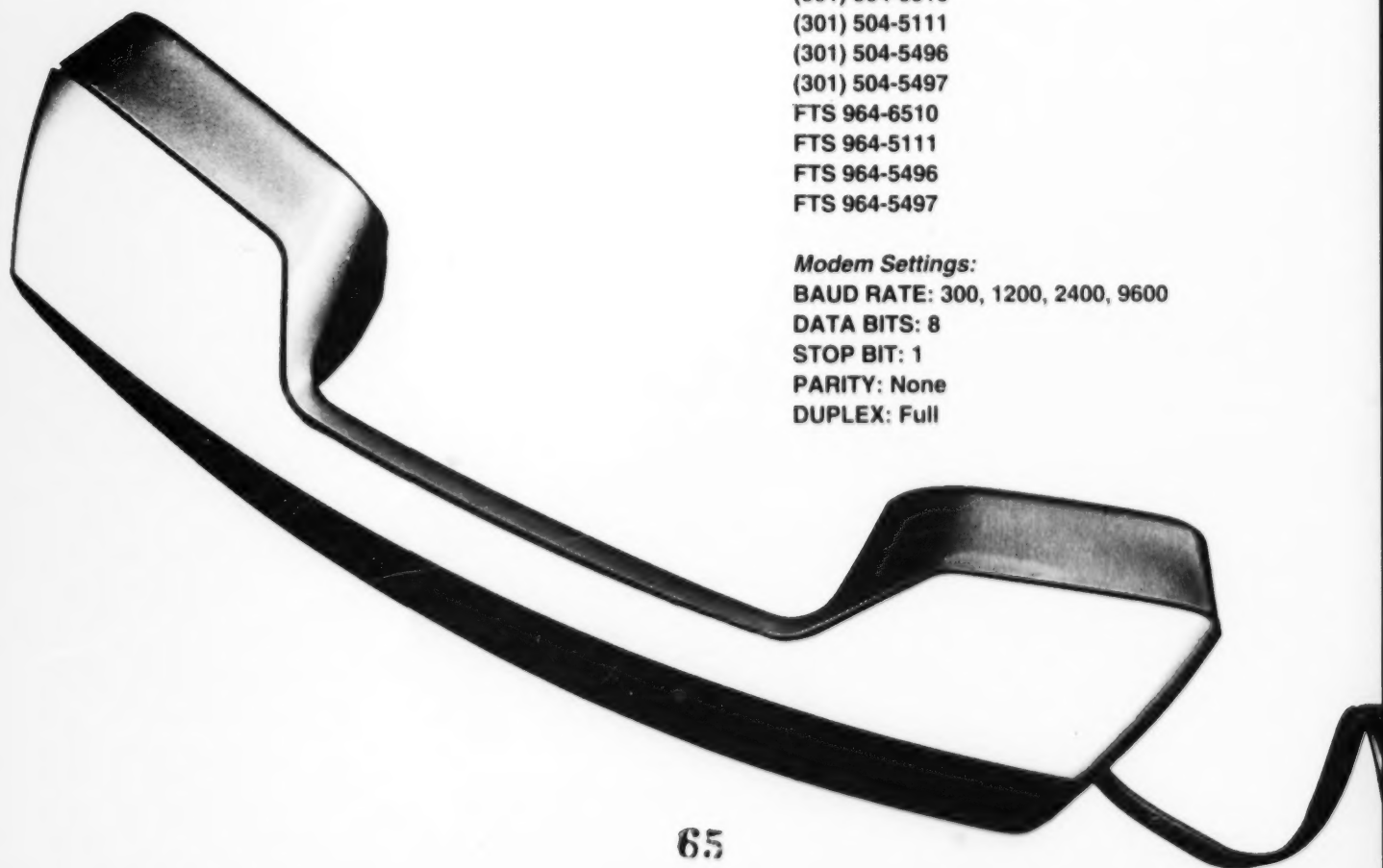
The center also publishes periodic updates and lists activities on the National Agricultural Library's electronic bulletin board, Agricultural Library Forum (ALF). Here's how you can access ALF, 24 hours a day, seven days a week:

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(301) 504-5111
(301) 504-5496
(301) 504-5497
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FTS 964-5111
FTS 964-5496
FTS 964-5497

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